



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (cwf)
FOLDER: K082423 - 716 pages
COMPANY: RADIANCY (ISRAEL) LTD. (RADIISRA)
PRODUCT: POWERED LASER SURGICAL INSTRUMENT (GEX)
SUMMARY: Product: NO!NO! SKIN

DATE REQUESTED: Jul 13, 2015

DATE PRINTED: Jul 13, 2015

Note: Printed



KSB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date 1/27/09

From DMC (HFZ 401)

Subject Premarket Notification Number(s) 1K052423 /AV

To Division Director SU / DORN

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s) Since a final decision has been rendered this record is officially closed

Please review the attached document and return it to the DMC with one of the statements checked below

Information does not change the status of the 510(k) no other action required by the DMC please add to image file (Prepare K 25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS

Additional information requires a new 510(k) however the information submitted is incomplete (Notify company to submit a new 510(k) [Prepare the K30 Letter on the LAN]

No response necessary (e.g. hard copy of fax for the truthful and accuracy statement 510(k) statement change of address phone number or fax number)

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a **CLIA CATEGORIZATION** the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a **CLIA CATEGORIZATION** however the information submitted is incomplete (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum

Reviewed by Kareem S Burney I concur with NR.

Date 2/25/09 Neil 2/25/09

(PINC)
2/25



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FDA CDRH D MC

Food and Drug Administration
Center for Devices and Radiological Health
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9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2009

Received

K9

Attn Mr Mark Melkerson Director Division of General Restorative and Neurological
Devices Office of Device Evaluation Center for Devices and Radiological Health

Re 510(k) Premarket Notification for the no!no! Skin™ Device #K082423

Dear Mr Melkerson

Enclosed please find three copies of the presentation we intend to make during the
meeting scheduled for February 17 2009 at 4 00 pm at the FDA office on 9200
Corporate Boulevard Rockville Maryland The presentation covers the following topics

(b)(4) CCI

- 1
- 2
- 3
- 4
- 5

6

(b)(4) CCI

Please refer any communications regarding this information to Zvi Ladin Ph D
Boston MedTech Advisors Inc 990 Washington Street Suite 204 Dedham MA 02026
Ph (781) 407 0900 / x104 FAX (781) 407-0901 Cell (617) 921 6400 E mail
zladin@bmtadvisors.com

Sincerely yours



Zvi Ladin PhD Principal Boston MedTech Advisors Inc for
Dolev Rafaeli CEO Radiancy Inc

Encl

- 1 Power Point presentation slides
- 2 Gold MH Sadick NS Bradshaw VL and Borng MM A randomized controlled double blind study of localized low heat treatment of acne lesions
Cosmetic Dermatology 20[8] 495-499 2007

Radiancy no!no!Skin™ OTC Acne Device (K082423)

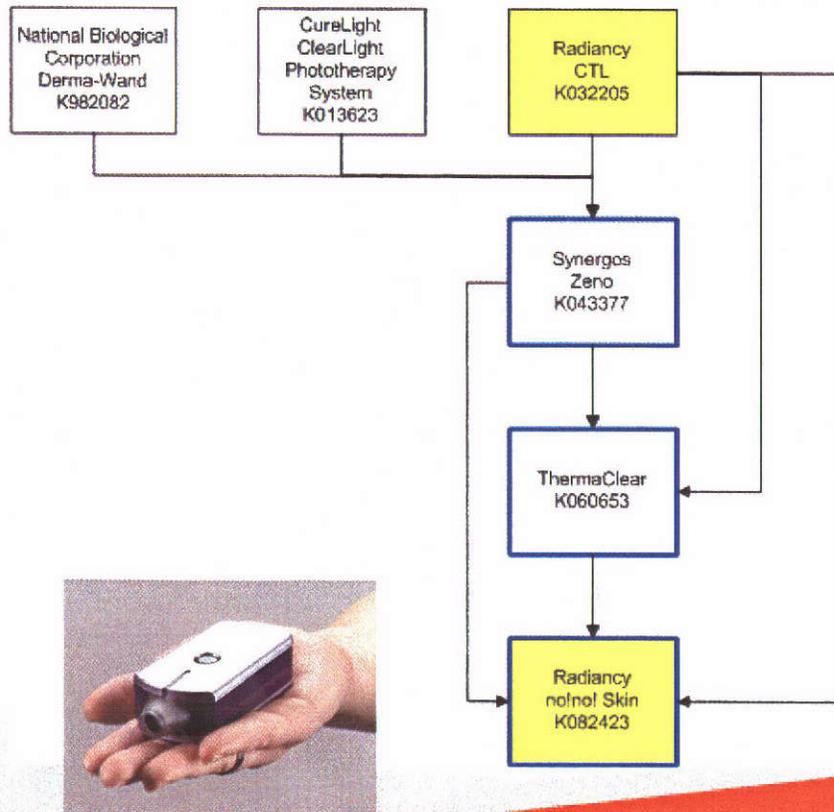


Summary of Clinical Study Results and Comparison to Predicate Devices

LHE RADIANCY™

Regulatory History of OTC Acne Treatment Devices

Predicate History



Technical Highlights – no!no! Skin

- Halogen Lamp
- Light and Heat energy
 - Same as Radiancey's CTL (K032205)
- Battery powered
- Skin and eye safe
 - Appendix attached

Clinical Study Protocol Highlights

- Clinical and Usability Protocols formulated following review by and discussions with the FDA
- Two scales used for efficacy evaluation:
 - VAS – Visual Analog Scale (4-point relative)
 - PLRS – Photographic Lesion Reference Scale (5-point absolute)
 - Two 'blinded' evaluators (principal investigator + independent evaluator)
- Primary end point
 - Time to Improvement (TI) based on VAS
- Secondary end points
 1. Time to resolution (TR) based on VAS
 2. TR based on patients' VAS (recorded in diaries)
 3. Change from baseline based on PLRS
- A two-center, randomized, placebo-controlled, double blind study

Clinical Investigators

Neil Sadick, MD, FAAD, FAACS, FACP, FACPh

- Titles include (among others):
 - Clinical Professor of Dermatology at Weill Cornell Medical College
 - President of the Cosmetic Surgery Foundation
 - Member of the Board of Examiners for the International Society of Hair Restoration Surgery
- Board certifications
 - Dermatology
 - Cosmetic Surgery
 - Internal Medicine
 - Hair Transplantation.
- Author, or co-author of:
 - more than 500 articles in peer-reviewed scientific journals
 - More than 75 chapters of medical books
 - Has written or edited more than 10 books on cosmetic surgery, hair, and vein treatment.
 - Guest lecturer at more than 500 medical seminar classes and workshops worldwide.

Zehava Laver, MD, PhD, MSc

- Titles include:
 - M.Sc in Micro Biology
 - Ph.D in Life Sciences
 - Former chief of the dermatological clinic ,Hadassa university hospital,Jerusalem,Israel.
 - Former research associate in the department of virology,Wiezmann Institute,Rehovot Israel.
- Board certified
 - Dermatology
 - Venereology
 - Hair Transplantation.
- Author, or co-author of:
 - More than 31 articles in peer-reviewed scientific journals
 - Guest lecturer at medical seminar classes and workshops worldwide

Study Protocol – Comparison to Predicates

	no!no! Skin	Zeno	ThermaClear
Lesion Selection	Patient – per FDA instruction	Clinical Staff	Clinical Staff
Lesion Treatment	Patient – per FDA instruction	Unblinded Administrator	Clinical Staff
Placebo	Yes	Yes	No
Number of Clinical Sites	2	1	1
Number of Patients	63	51	46
Number of Lesions	252	102	430
Duration of Study [days]	5	14	5
Blinding	Double	Double (Unblinded Treatment)	Only Evaluation
Method of Evaluation	Photographs	Photographs	Photographs
Number of Evaluators	2	1(?)	2
Treatment Duration	2 X 10 s	150 s	2 s
Number of Treatments	8	3	5

Study Results Based on PLRS

- Following FDA's correspondence (10/21/2008), lesion resolution is the **ONLY** acceptable measure of effectiveness. Therefore, effectiveness data presented:
 - Percentage of lesions fully resolved
 - Time to resolution
 - Percentage of lesions fully and almost resolved

	No!No! Skin	Zeno (white paper)	ThermaClear (web summary)
Percentage of Lesions Fully Resolved by day 5	50%	55%	44%
Kaplan Meier Mean Time to Resolution [days]	3.3	4	NA
Percentage of Lesions Fully Resolved and almost resolved by day 5	67%	NA	NA

Summary of FDA Correspondence - I

9/24/2008 – FDA Request for Additional Information	10/2/2008 – Sponsor Response
<ul style="list-style-type: none"> • VAS not acceptable 	<ul style="list-style-type: none"> • PLRS analysis provided
<ul style="list-style-type: none"> • Number of patients with overall improvement (most lesions improved) based on PLRS 	<ul style="list-style-type: none"> • 87% of subjects improved by at least 1 point in majority of lesions
<ul style="list-style-type: none"> • Number of lesions improved by 1 point based on PLRS 	<ul style="list-style-type: none"> • 73% of all lesions improved by at least 1 point
<ul style="list-style-type: none"> • Software documentation 	<ul style="list-style-type: none"> • Software documentation pointers (original submission)
<ul style="list-style-type: none"> • Risks to skin and eye 	<ul style="list-style-type: none"> • Additional information on device's safety
<ul style="list-style-type: none"> • Labeling changes 	<ul style="list-style-type: none"> • Labeling changes as requested

Summary of FDA Correspondence - II

10/21/2008 – FDA Request for Additional Information	10/23/2008 – Sponsor Response
<ul style="list-style-type: none"> • Lesion improvement is not an endpoint used to support requested indication 	<ul style="list-style-type: none"> • Lesion resolution analysis provided using PLRS
<ul style="list-style-type: none"> • Time to resolution required as study endpoint 	<ul style="list-style-type: none"> • Time to resolution based on the Kaplan Meier curves provided
<ul style="list-style-type: none"> • Statistically significant difference between active and placebo devices has to be shown 	<ul style="list-style-type: none"> • Statistically significant difference between lesions treated by active and placebo devices documented: <ul style="list-style-type: none"> ▪ Percentage of lesions cleared ▪ Clearance rate ▪ Time to resolution
<ul style="list-style-type: none"> • OTC labeling issues identified and will be disclosed following resolution of device's effectiveness 	

Summary of FDA Correspondence - III

12/3/2008 – NSE Letter	12/18/2008 – Sponsor Response
<ul style="list-style-type: none"> • Performance data submitted did not demonstrate same safety and effectiveness as legally marketed devices 	<ul style="list-style-type: none"> • Efficacy comparison to predicate devices showed similar rate of complete clearance • No safety issues
<ul style="list-style-type: none"> • Device classified as class III 	
<ul style="list-style-type: none"> • PLRS based analysis of time to resolution needed 	<ul style="list-style-type: none"> • PLRS based analysis of time to resolution provided in 10/23/2008 response
<ul style="list-style-type: none"> • Deficiencies in past responses to requests for additional information <ul style="list-style-type: none"> ▪ 9/25/2008 – Time to Improvement data ▪ 10/11/2008 – Direct comparison of time to resolution to predicate devices 	<ul style="list-style-type: none"> • Past responses: <ul style="list-style-type: none"> ▪ 9/25/2008 – Analysis of improvements in lesions and patients provided <u>per specific FDA's request</u> ▪ 10/21/2008 correspondence assumed (no correspondence dated 10/11/ 2008) ▪ Lesion resolution information provided per specific FDA's request ▪ <u>No specific request issued for direct comparison to predicate devices</u>

Basis for FDA's NSE Decision

- “The reason for this failure is that by day 5 the OTC predicate devices were able to show complete resolution (the lesions were either fully resolved or almost resolved) of the lesions using the active device in their clinical study, while your device does not show complete resolution of the lesions.”

Comparison to Placebo and to Predicates

	No!No! Skin	Zeno (white paper)	ThermaClear (web summary)
Percentage of Lesions Fully Resolved by day 5	50%	55%	44%
Kaplan Meier Mean Time to Resolution [days]	3.3	4	NA
Percentage of Lesions Fully Resolved and almost resolved by day 5	67%	NA	NA

- Similar fraction of lesions completely resolved – compared to both predicates
- Faster time to resolution than Zeno
- Statistically significant difference between active and placebo arms.

Zeno Based on Gold & Sadick, 2007

Trial highlights	Zeno
Blinding	Double
Placebo	Yes
Treatments	3X120s (80% of original duration)
Lesions Improved or Resolved Sooner with Device % (# / total)	50% (7 / 14)
Lesion Improved or Resolved Sooner with Placebo	29% (4 / 14)
No Difference Between Device and Placebo	21% (3 / 14)

Summary of Radiancy's Position

- The no!no!Skin clinical study
 - Followed FDA approved protocol including multiple quantitative efficacy measures
 - Statistically significant differences between active and placebo arms
- no!no! Skin effectiveness is substantially equivalent to results obtained with the Zeno and Thermaclear devices
- Radiancy therefore respectfully requests the FDA to reconsider the NSE decision

Appendix

14



Technical Comparison to Predicate Devices

Feature	<i>no!no! Skin</i> ™	Zeno™	ThermaClear™
FDA Clearance	K082423 OTC	K043377 OTC	K060653 OTC
Intended Use	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne
Energy Source	Light & Heat (LHE) Halogen lamp	Low level heat, 49.4°C Heating element	Nichrome heat element
Wavelengths	450-2000 nm	NA	NA
Energy delivery duration	10 sec	2.5 min	2 sec
Spot size	8 mm dia. 50 mm ²	0.25 in (71 mm ²)	0.5 in (127 mm ²)
Max fluence	6 J/cm ²	NA	NA
Electical input	Rechargeable batteries	Rechargeable batteries	2 AA Batteries
Dimensions	145 X 36 X 26 mm	114 X 38 X 13 mm	124 X 53 X 28 mm

Skin and Eye Safety

		no!no! Skin	Comments
Power Source		Rechargeable Batteries	Same as Zeno 2 AA for ThermaClear
Maximim Fluence		6 J/cm ²	Same as ClearTouch Lite™ (K060411)
Maximim Skin Temperature		40.4°C	49.4°C – Zeno Element
Eye Safety: Max Values / Exposure Limit	Photoretinitis of Retina [W/cm ²]	0.6 / 250	Actual power density delivered / Exposure limit values Based on DIRECTIVE 2006/25/EC – detailed analysis provided in October 2, 2008 correspondence
	Retinal Burn [W/cm ²]	0.6 / 707	
	Corneal Burn – Cataractogenesis of Cornea Lens [W/cm ²]	0.6 / 6.4	

A Randomized, Controlled, Double-blind Study of Localized Low-Heat Treatment of Acne Lesions

Michael H. Gold, MD; Neil S. Sadick, MD; Virginia L. Bradshaw, NP-C; Molly M. Boring, FNP-C

Zeno™, a new handheld device, produces low-level heat (controlled to 46.5–49.0°C) that may be applied to acne vulgaris lesions via a small metal tip. The purpose of this study was to evaluate the efficacy and safety of Zeno when it was used at a treatment time 20% lower than in an earlier study. Our study was conducted at 2 clinical sites with a total of 15 subjects and was randomized and controlled within a single subject. Eligible subjects had 2 similar acne lesions on the face. One lesion was treated with Zeno and the other with a placebo device; both lesions were treated twice on the first day and once on the second day. Follow-up assessments were made immediately before the second treatment (typically 4 hours after the first treatment) and the third treatment (typically 24 hours after the first treatment) and on day 5. The primary end point was the time to resolution of treated acne lesions. Secondary end points, including investigator and subject assessments on a blemish-change assessment scale, were evaluated. Any adverse events were reported. One subject failed to appear for appointments and was lost to follow-up and not included in the analysis. In 7 of the remaining 14 subjects, lesions improved or resolved sooner with Zeno than with placebo. In 3 subjects, improvement or resolution times were the same; in the 4 remaining subjects, placebo-treated lesions improved earlier. Adverse events were not observed with each device in the 14 subjects. Zeno appears to be an effective, safe take-home device for use alone or as adjunctive therapy with prescribed medications. There may be a link between dosage and efficacy.

Dr. Gold is Clinical Assistant Professor, Department of Dermatology, Vanderbilt University School of Medicine and Vanderbilt School of Nursing, Nashville, Tennessee, and Medical Director, Gold Skin Care Center and Tennessee Clinical Research Center, Nashville. Dr. Sadick is Clinical Professor of Dermatology, Weill Medical College of Cornell University, and in Private Practice, Sadick Dermatology, New York, New York. Ms. Bradshaw and Ms. Boring are Nurse Practitioners, both at Gold Skin Care Center, Nashville.

Dr. Gold was a consultant for Tyrell, Inc, at the time of this study. Dr. Gold and Dr. Sadick have received research support from Tyrell, Inc.

Acne vulgaris affects 70% to 80% of people aged 11 to 30 years.¹ A variety of oral, systemic, and physical methods, alone or in combination, are available for treatment (Table 1). Choice of treatment depends on grade and duration of acne, scarring, and a patient's psychological health.² Topical medications suppress lesions by no more than 60% and often produce an irritating dermatitis, thus reducing compliance.³ Antibiotic use produces resistant strains of *Propionibacterium acnes*.³⁻⁵ These limitations, as well as increasing prevalence of antibiotic-resistant *P acnes*

LOW-HEAT TREATMENT OF ACNE

TABLE 1

Acne Treatments

Chemical

Retinoids
 Adapalene
 Antibiotics
 Benzoyl peroxide
 Azelaic acid
 Salicylic acid

Physical

Comedone extraction
 Electrocautery
 Chemical peels
 Light energy
 Laser energy
 Photodynamic therapy
 Glucocorticoids*

Hormonal

Androgens
 Antiandrogens
 Estrogens
 Oral contraceptives

*Glucocorticoids are considered physical treatments when given intralesionally.

TABLE 2

Demographics of Subjects Treated With Zeno™ and Placebo for Facial Acne Lesions

Subject	Age, y	Sex	Race
1	20	Female	Hispanic
2	30	Female	African American
3	27	Female	White
4	29	Female	White
5	30	Female	White
6	30	Female	White
7	21	Female	White
8	34	Female	White
9	43	Female	White
10	18	Male	White
11	34	Female	White
12	26	Female	European
13	33	Female	White
14	22	Female	East Indian*

*Refers to an ethnic group based in Mumbai, formerly known as Bombay, India.

strains, necessitate new therapies for mild to moderate acne.

To meet this need, Bruce et al⁶ postulated that targeting *P acnes* within developing acne lesions might accelerate the resolution of these lesions and that *P acnes* colonies would be susceptible to low-level intermittent heat. Their preclinical experiments showed that the amount of heat required to reduce colony counts from treated anaerobic cultures of *P acnes* was tolerable to human skin. These researchers then developed a handheld prototypic device with a small treatment tip that could deliver a controlled amount of heat to an individual acne lesion.

After optimizing temperature level, exposure time, and treatment frequency, the researchers conducted a double-blind, placebo-controlled clinical trial of the prototypic device in 50 human subjects with mild to moderate acne. In that clinical trial, each heat dose was 2.5 minutes in duration. The results showed that

treatment with this handheld device, which delivered heat with a proprietary technology (ClearPoint™), improved the resolution time for individual acne lesions compared with the placebo device.⁶

This article outlines a study evaluating the efficacy and safety of Zeno™ when it was used at a treatment time 20% lower than in the study by Bruce et al.⁶

MATERIALS AND METHODS

The study was conducted at 2 clinical sites with 15 subjects altogether and was randomized and controlled within a single subject. Eligible subjects had 2 similar acne lesions on the face. One lesion was treated with Zeno and the other with a placebo device; both lesions were treated twice on the first day and once on the second day. Follow-up assessments were made immediately before the second treatment (typically 4 hours after the first treatment) and the third treatment (typically 24 hours after the first treatment) and on day 5. The primary end point was the time to resolution of treated acne lesions. Secondary end points, including investigator and subject assessments on

TABLE 3

Investigator-Subject Assessments of Treatment With Zeno™ and Placebo for Facial Acne Lesions*

Patient	Investigator						Subject						First to Improve/Resolve
	Lesion 1			Lesion 2			Lesion 1			Lesion 2			
	A1	A2	A3	A1	A2	A3	A1	A2	A3	A1	A2	A3	
1 [†]	NC	I	R	NC	I	R	NC	I	I	NC	I	R	Placebo
2 [†]	NC	I	I	NC	NC	I	NC	I	I	NC	I	I	Same
3 [†]	NC	I	R	NC	NC	I	NC	I	R	NC	I	I	Zeno
4 [†]	NC	I	I	NC	I	I	I	I	NC	I	I	R	Placebo
5 [‡]	I	I	R	I	R	R	NC	I	NA	I	R	NA	Zeno
6 [‡]	I	I	R	I	NC	I	I	I	R	NC	NC	R	Zeno
7 [‡]	NC	NC	I	NC	NC	I	NC	NC	NC	NC	NC	NC	Same
8 [‡]	NC	I	I	NC	I	R	NC	I	R	NC	I	R	Zeno
9 [‡]	NC	NC	R	NC	I	R	NC	NC	I	NC	I	I	Zeno
10 [‡]	I	R	R	I	I	R	NC	NC	I	I	I	I	Zeno
11 [‡]	NC	R	R	I	R	R	NC	R	R	NC	I	I	Zeno
12 [‡]	NC	I	I	NC	I	I	NC	I	I	NC	I	I	Same
13 [‡]	NC	I	I	NC	NC	I	NC	I	I	NC	NC	NC	Placebo
14 [‡]	NC	NC	NC	NC	I	I	NC	I	NC	NC	I	I	Placebo

*A1 indicates evaluation before second treatment; A2, evaluation before third treatment; A3, evaluation at day 5; NC, no change; I, improved; R, resolved; NA, not available.

[†]Lesion 1 treated with Zeno; lesion 2 treated with placebo.

[‡]Lesion 1 treated with placebo; lesion 2 treated with Zeno.

a blemish-change assessment scale, were evaluated. Any adverse events were reported. The study was approved by the IntegReview institutional review board. All subjects provided signed informed consent.

SUBJECTS

Eligible subjects had 2 similar facial acne lesions (papules or cysts of similar pathological state and duration) and provided a complete medical history and list of medications taken. Subject demographics are shown in Table 2. Excluded subjects were those who were taking oral antibiotics; had severe acne requiring prescription medication; had known skin sensitivity to heat, sunburn, or chemical agents; had a rash from known metallic materials; had been treated with topical facial antibiotics within 24 hours of the procedure; or were unable to understand the informed consent procedure without

language assistance. Each subject was asked to record (in a diary) changes in tenderness and appearance of each lesion during the morning and evening of each day of the study. Tenderness was graded as extreme or absent. Changes in lesion appearance were recorded as worsened, no change, improved, or resolved. Subjects were asked to record data until both lesions resolved or until the fourteenth day after the first treatment, whichever came first.

STUDY DESIGN

The study was randomized and controlled within a single subject. One lesion was treated with Zeno set to deliver a shorter-than-normal treatment of 2 minutes, the other with a placebo device that delivered no heat. Treatments were given twice on the first day and once on the second day. The primary end point was the time to resolution of treated lesions. Secondary end points, including investigator and

LOW-HEAT TREATMENT OF ACNE

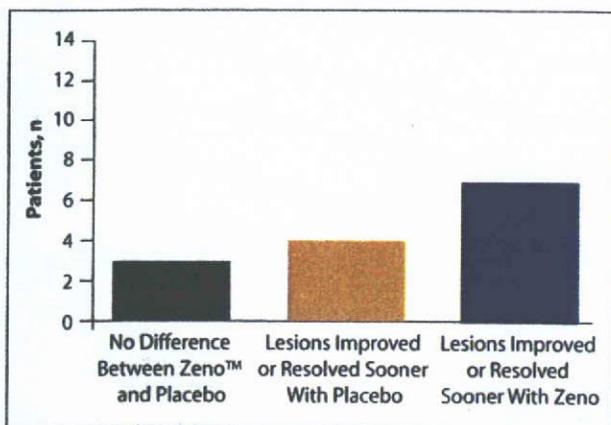


Figure 1. Comparative performance of Zeno™ versus placebo in 14 subjects at day 5.

subject assessments on a blemish-change assessment scale, were evaluated. Any adverse events were reported.

PROTOCOL

On day 1, the investigator selected, evaluated, and, if possible, obtained photographs of 2 facial acne lesions on each subject. The first treatment was given on the morning of day 1. The investigator applied Zeno to 1 lesion for 2 minutes and the placebo device to the other lesion for 2 minutes. The second treatment was administered in the same manner 1 to 4 hours after the first; the third treatment was given approximately 24 hours after the first.

The investigator assessed changes immediately before the second and third treatments and on day 5. Subjects were told that discomfort, temporary local redness, and skin drying, flaking, and peeling may occur with treatment.

PRELIMINARY DATA ACQUISITION

The demographics of subjects with complete data (n=14; age, 28.4 ± 6.7 years [mean \pm SD]) are shown in Table 2. One subject failed to appear for appointments and was lost to follow-up and not included in the analysis. Subjects ranged in age from 18 to 43 years. Baseline lesion tenderness and use of isotretinoin were recorded. Subjects washed their faces at least twice daily and were not restricted in their use of over-the-counter facial products (acne creams, facial cleansers, astringents, makeup removers, moisturizers, soaps, or sunscreens). Subjects recorded the names of each product they used and how often they used it. One subject had used isotretinoin previously.

RESULTS

Subjects were generally pleased with their results (Table 3). In 7 of the 14 subjects, lesions improved or resolved sooner with Zeno than with the placebo device. In 3 subjects, improvement or resolution times were the same; in the 4 remaining subjects, placebo-treated lesions improved earlier. The results are presented graphically in Figure 1. In most cases, the investigator and subject agreed on the improvement and resolution times.



Figure 2. Subject just before treatment with Zeno™ (subject's right side) and placebo (subject's left side) for acne lesions between the brow (A). The Zeno-treated lesion resolved 3 days earlier than the placebo-treated lesion. Lesions between the subject's brow immediately before the second treatment of the first day (B). The white circular spot has been placed just above the location of the placebo-treated lesion at the end of the treatment period (day 5)(C). The white circular spot has been placed just above the location of the Zeno-treated lesion at the end of the treatment period (day 5)(D). Photographs courtesy of Michael H. Gold, MD.

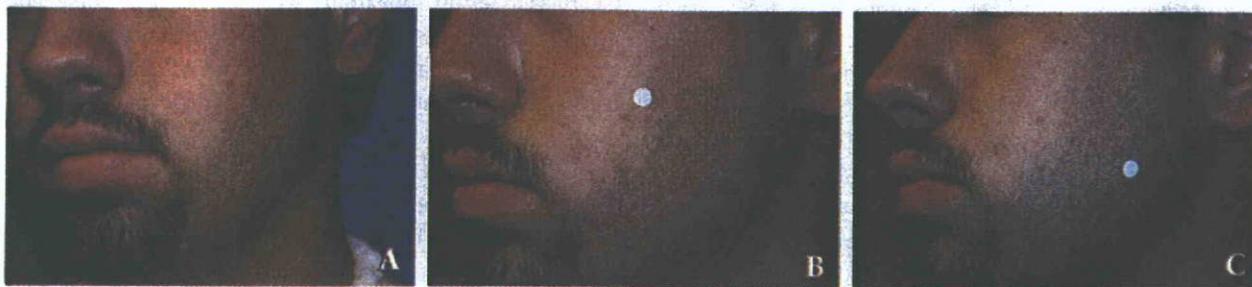


Figure 3. Subject treated with Zeno™ (lesion between the nasolabial fold and the ear) and placebo (the lower lesion to the rear of the cheek) for acne lesions on the left cheek (A). The Zeno-treated lesion resolved 3 days earlier than the placebo-treated lesion. The white circular spot has been placed above the location of the Zeno-treated lesion just before the third treatment (B) and above the location of the placebo-treated lesion just before the third treatment (C). Photographs courtesy of Michael H. Gold, MD.

LOW-HEAT TREATMENT OF ACNE

Lesion tenderness was absent or slight in 11 subjects and changed little with continued Zeno or placebo treatment. In 1 subject extreme initial tenderness in both lesions improved with treatment (Zeno and placebo). In another subject moderate tenderness persisted throughout the treatment period for both lesions. Adverse events with each device were not observed by investigator or subjects. Clinical examples are shown in Figures 2 and 3.

COMMENT

In an earlier double blind placebo controlled clinical trial Bruce et al⁶ used a prototypic Zeno device to treat 51 subjects with mild to moderate acne who were not using systemic medications. Treatment time was approximately 2.5 minutes, 20% longer than the 2 minutes used in the present study. The median time to resolution for Zeno treated lesions was 96.7 hours (\approx 4 days) compared with 151.8 hours ($>$ 6 days) with the placebo device which as with the present study did not deliver heat. Zeno treated lesions also showed improvement sooner than placebo treated lesions (median 12.8 hours vs 35.6 hours respectively). This suggests a dose response relationship that warrants further study.

CONCLUSION

Based on these preliminary results Zeno appears to be effective in improving or resolving mild to moderate acne lesions more quickly in approximately 50% of treated subjects when compared with placebo. Zeno seems to be an effective safe take home device for use alone or as adjunctive therapy with prescribed medications. In addition the level of efficacy suggested by these preliminary results when compared with the results from an earlier clinical trial at a higher dosage may indicate a link between dosage and efficacy. Further studies are warranted to confirm this link.

REFERENCES

1. Krautherm A, Gollnick HP. Acne: topical treatment. *Clin Dermatol* 2004; 22: 398-407.
2. Hanna S, Sharma J, Klotz J. Acne vulgaris: more than skin deep. *Dermatol Online J* 2003; 9: 8.
3. Cunliffe WJ, Holland DB, Clark SM, et al. Comedogenesis: some new aetiological, clinical and therapeutic strategies. *Br J Dermatol* 2000; 142: 1084-1091.
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5. Dreno B, Legallou F, de Sainte Marie I, et al. Prevalence of erythromycin resistant propionibacteria and *Staphylococcus epidermidis* in acne subjects in France [abstract]. *J Invest Dermatol* 1997; 108: 379.
6. Bruce S, Conrad C, Peterson RD, et al. Significant efficacy and safety of low level intermittent heat in subjects with mild to moderate acne [white paper]. AcneClearingHouse Web site. Available at http://acneclearingdevice.com/Zeno_White_Papers.pdf. Accessed June 25, 2007. ■

NO! NO! SKIN
(K082423)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2009

Radiancy (Israel) LTD.
c/o Boston MedTech Advisors, Inc.
Zvi Ladin, PhD, Principal
990 Washington Street, Suite 204
Dedham, MA 02026

Re: k082423
No! No! Skin™
Appeal of Not Substantially Equivalent Decision
Dated: December 18, 2008
Received: December 19, 2008

Dear Dr. Ladin:

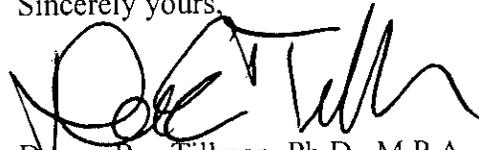
This letter is in response to your letter of appeal dated December 18, 2008, requesting that the not substantially equivalent (NSE) decision for the above reference premarket notification submission (510(k)) that was issued on December 3, 2008, from Mark N. Melkerson, Director, Division of General, Restorative, and Neurological Devices (DGRND), now the Division of Surgical, Orthopedic, and Restorative Devices (DSORD), Office of Device Evaluation, be reviewed by the next level supervisor. I have reviewed this appeal under our regulations found in Title 21 of the Code of Federal Regulations Part 10.75 Internal agency review of decision, as the next level supervisor.

After reviewing your letter of appeal, including my review of the 510(k), meeting internally on several occasions with DSORD, and discussing your appeal with you and your clients on February 17, 2009, and consulting with my clinical deputy, I have determined that your device has performance that is substantially equivalent to predicate devices cleared for over-the-counter used in the treatment of mild to moderate acne. My decision is based on the fact that your 510(k) contained data from a randomized, sham-controlled, double-blinded, clinical trial demonstrating that your device provides a statistically and clinically significant improvement in the time to improvement and time to resolution of mild to moderate acne when compared to sham treatment, as assessed by blinded investigators. I have determined that these data are sufficient to provide a reasonable assurance of the safety and effectiveness of your device for the purposes of demonstrating substantial equivalence. Therefore, I am overturning the NSE decision from DSORD and issuing a letter of substantial equivalence (enclosed) for the above referenced device as described in the 510(k).

Page 2 – Zvi Ladin, Ph.D.,Principal

If you have any questions regarding this letter, please contact Heather S. Rosecrans,
Chief, 510(k) Staff at (240) 276- 4021.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Denna-Bea Tillman". The signature is fluid and cursive, with a large initial "D" and "T".

Denna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Radiancy (Israel) LTD.
c/o Boston MedTech Advisors, Inc.
Zvi Ladin, PhD, Principal
990 Washington Street, Suite 204
Dedham, MA 02026

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2009

Re: k082423

Trade/Device Name: No! No! Skin™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in
Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 23, 2008
Received: October 24, 2008

Dear Dr. Ladin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

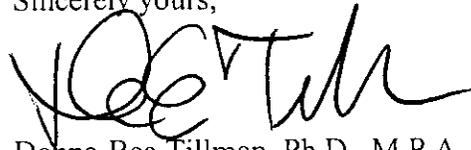
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -- Zvi Ladin, Ph.D., Principal

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.A.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k082423

Device Name: No! No! Skin™

Indications For Use: No! No! Skin is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

The product code is: GEX

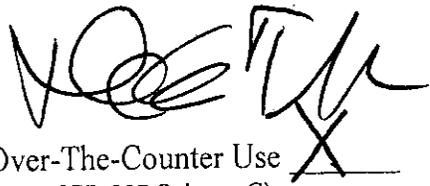
Regulation number: 21 CFR 878.4810

Regulation name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory class: II

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use 
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

FAX HEADER 1: FDA-CDRH-ODE-POS
FAX HEADER 2:

TP	MODE	DATE/TIME	ADDRESS	RESULT	PAGE
F	ODE	JUL. 8. 2009 12:39PM			

7016	MEMORY TX		+17814070901	OK	6/6

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-3) NO ANSWER

F-2) BUSY
E-4) NO FACSIMILE CONNECTION



FAX COVER SHEET

Fax Numbers:
240-276-4009 or 240-276-4025
Voice Phone Number:
240-276-4040

DHHS/PHS/FDA/CDRH
Office of Device Evaluation
Program Operations Staff (HFZ-404)
9200 Corporate Boulevard
Rockville, MD 20850

TO: *Zvi Lachin*
FROM: *Donna Dea Tillman*

Comments:

Number of Pages (Including Cover Sheet): *6*

"This document is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone and return it to us at the above address by mail. Thank you."

(Please include 510(k) number here: K)

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

Boilerplate Last Updated: 6/18/09 – Brandi Stuart

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Review of Request for Supervisory Review

Date: July 7, 2009

From: Donna-Bea Tillman, Ph.D, M.P.A
Director, Office of Device Evaluation

Re: Appeal of K082423, Radiancy No!No! device for the treatment of acne
NSE letter dated December 3, 2008

Action: Reverse NSE and issue SE letter

Background

The Radiancy No!No! (NoNo) is a battery-powered, handheld device indicated for the OTC treatment of individual lesions in mild to moderate inflammatory acne. The device uses a halogen lamp to deliver energy in the 450-2000nm wavelength range to a 50 mm² spot. Treatment time is 10 seconds, and the user is instructed to apply two treatments to each lesion twice a day.

The sponsor conducted a randomized, double-blinded, placebo controlled study of 63 subjects to support clearance. The device was determined to be NSE due to failure to demonstrate equivalent performance to the predicate device, and a letter was issued by DGRND dated December 3, 2008.

The sponsor requested that DGRND reconsider the decision in a letter dated December 18, 2008. Mark Melkerson upheld the decision, and the company appealed to me as the next level supervisor. We met with the firm February 17, 2009. After that meeting I requested that DGRND reconsider their decision. On March 9, 2009, I received an email from Mark Melkerson stating that the branch and division would stand by their original decision. Markham Luke, MD, ODE clinical deputy and I had a meeting and several further email exchanges with DGRND regarding this file, in particular, over why it was not appropriate to directly compare the results of this study to the results of the Zeno (predicate device) study. On May 4, 2009, I received a final email from Mark Melkerson, continuing to uphold the decision.

Review Analysis

Predicate Devices

There are two predicate devices (both with OTC indications) that are the most relevant to this submission: the Tyrell “Zeno”, and the DermaCare “Thermaclear”. I will begin by summarizing the basis for the clearance of each of these devices.

1. Tyrell Zeno (K043377). Reviewer: Richard Felten. There was not a clinical review of this 510k. SE letter issued 6/1/2005.

The Zeno device uses low level heat (119 degF) to treat individual lesions in mild to moderate inflammatory acne. The device is battery powered, and treats a 71 mm² spot size. Treatment is 2.5 minutes per lesion, and the treatment paradigm is two treatments on the first day, and one treatment on the second. This was the first “heat-based” device to treat acne (predicates were low-level light devices).

The study was a double-blinded, randomized controlled trial of 51 subjects with mild to moderate acne. Of note (and as opposed to the NoNo device), subjects with pustular acne were excluded. The investigator selected two comparable blemishes, and one was treated with the Zeno device, the other was treated with a placebo device (Note: The placebo device only achieved a temperature of 94 degF, while the Zeno device reached 119 degF). Photographs of each blemish were taken at each follow-up visit.

Patients maintained a patient diary in which they recorded an assessment of each blemish on each day. The four types of responses were: resolved, improved, no improvement, or worsened. The first day that a blemish was rated as resolved was used to determine the time to resolution. The time to resolution was the pre-specified primary endpoint for the study. Secondary efficacy endpoints included the blinded investigator’s assessment of the treated area. Adverse events were also recorded.

The primary endpoint of the study was met. The median time to resolution for the Zeno device (in hours, and as reported in the patient diary) was 90 (95% CI [69, 118]) as compared to 140 [119, 166], with a $p < 0.0020$ (log-rank test). The percentage of blemishes that resolved or improved, as assessed by the blinded investigator, was also significantly better for the Zeno device (100% for the Zeno device, and 77% for the control at day 5).

It appears from the record that the reviewer primarily relied on the blinded investigator assessment of the percentage of lesions improved or resolved by day 5, and that these results are comparable to those observed for other devices previously cleared for the treatment of facial acne.

2. Dermacare Thermaclear (K060653). Reviewer: Richard Felten. There was not a clinical review of this 510k.

The Thermoaclear device uses a nichrome heating element to apply thermal energy to a 127 mm² spot to treat individual pimples in mild to moderate inflammatory acne. Peak temperatures at the skin is 150 degF, and the duration of treatment is 2 sec.

The study included 43 patients with 278 treated lesions. However, because control lesions were not assessed for all of these patients, the review focused on 14 subjects who had 53 lesions treated and 51 control lesions. [Note: In this study, the control lesions did not receive any treatment] Lesions were evaluated by baseline, and on a daily basis out to five days. Assessments were made by a blinded investigator based on a review of photographs. A severity scale of 0-3 was used, with 0 being a non-inflamed lesion, and 3 being a severe visible lesion raised 2mm or more above the skin with erythema extended greater than 1mm. Although not explicitly stated, it appears that the primary endpoint was lesion score at day 5.

At day five, the average lesion score was 0.83 for the treatment group (baseline 1.58) and 1.18 for the control group (baseline 1.62). The reviewer notes that “even non-treated lesions improve over time...however, the treated lesions show a greater degree of improvement”.

A second analysis was performed looking at lesion response, where a severity score of 0 represents “resolved”, and a day 5 score that is lower than baseline represents “improvement”.

	Treated group	Control group
Resolved	38%	17%
Improved	26%	29%
Resolved/Improved	64%	46%

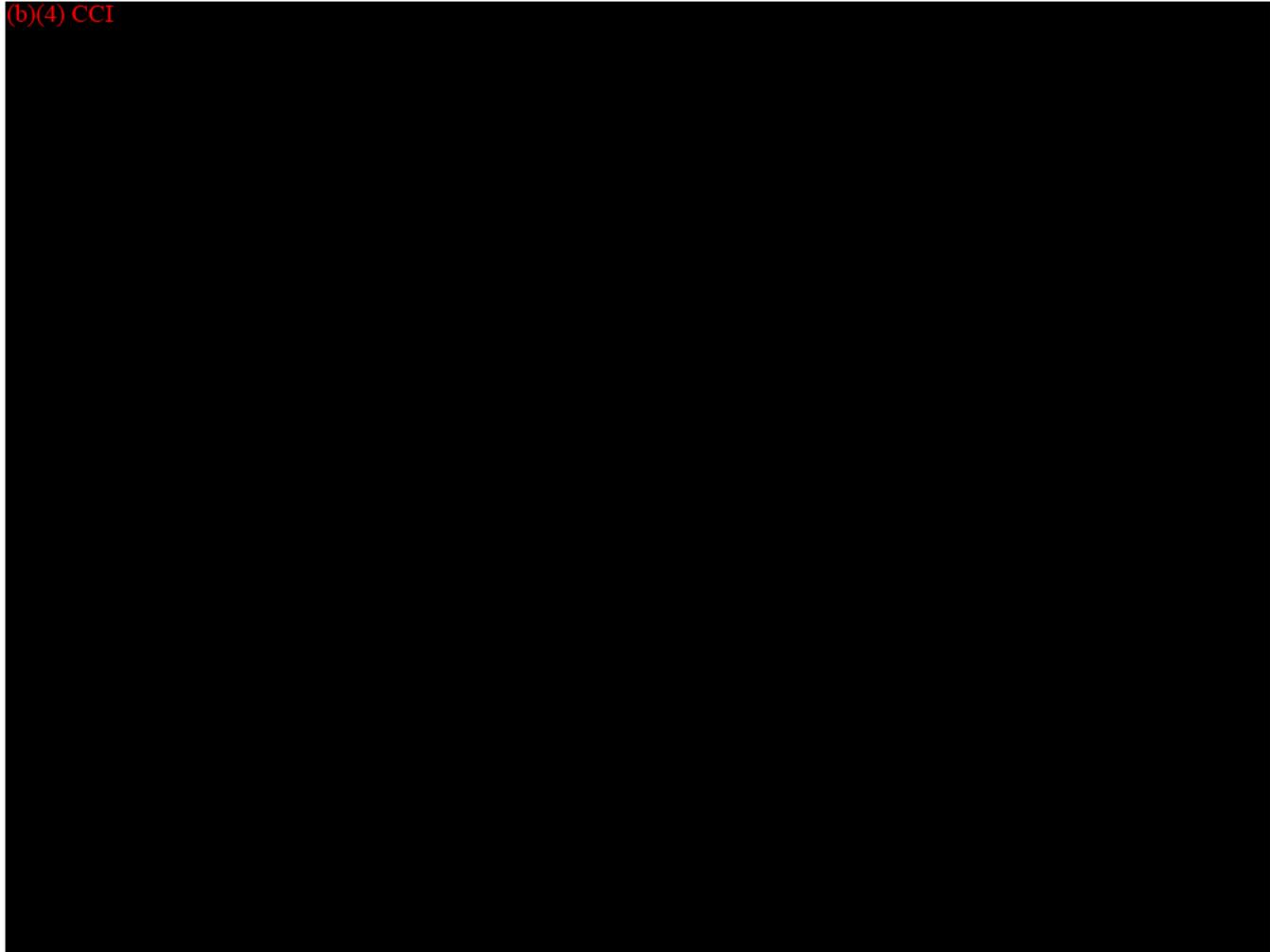
The reviewer notes that “Again this indicates that treatment does provide benefit with a greater number of lesions in the treated group having a score of 0 [resolved] by day 5”. The reviewer goes on to note that: “In terms of comparison to the predicate device, the Zeno device, both of these devices essentially reduce the time to clearance of acne lesions. The endpoint for the Zeno study was time to clearance with the treated lesion demonstrating a quicker time to clearance”.

Note: Although not explicitly mentioned by the reviewer, the data table provided by the firm (IMAGE p.21) shows that even in the treated arm, some subjects have a severity score at day 5 that is greater than the score at baseline (e.g., patient 140 has a lesion that is rated “1” at baseline at “2” at day 5, and patient 144 has a lesion that is “2” at baseline and “3” at day 5). In other words, some of the treated patient get worse. This will be important in considering the NoNo results.

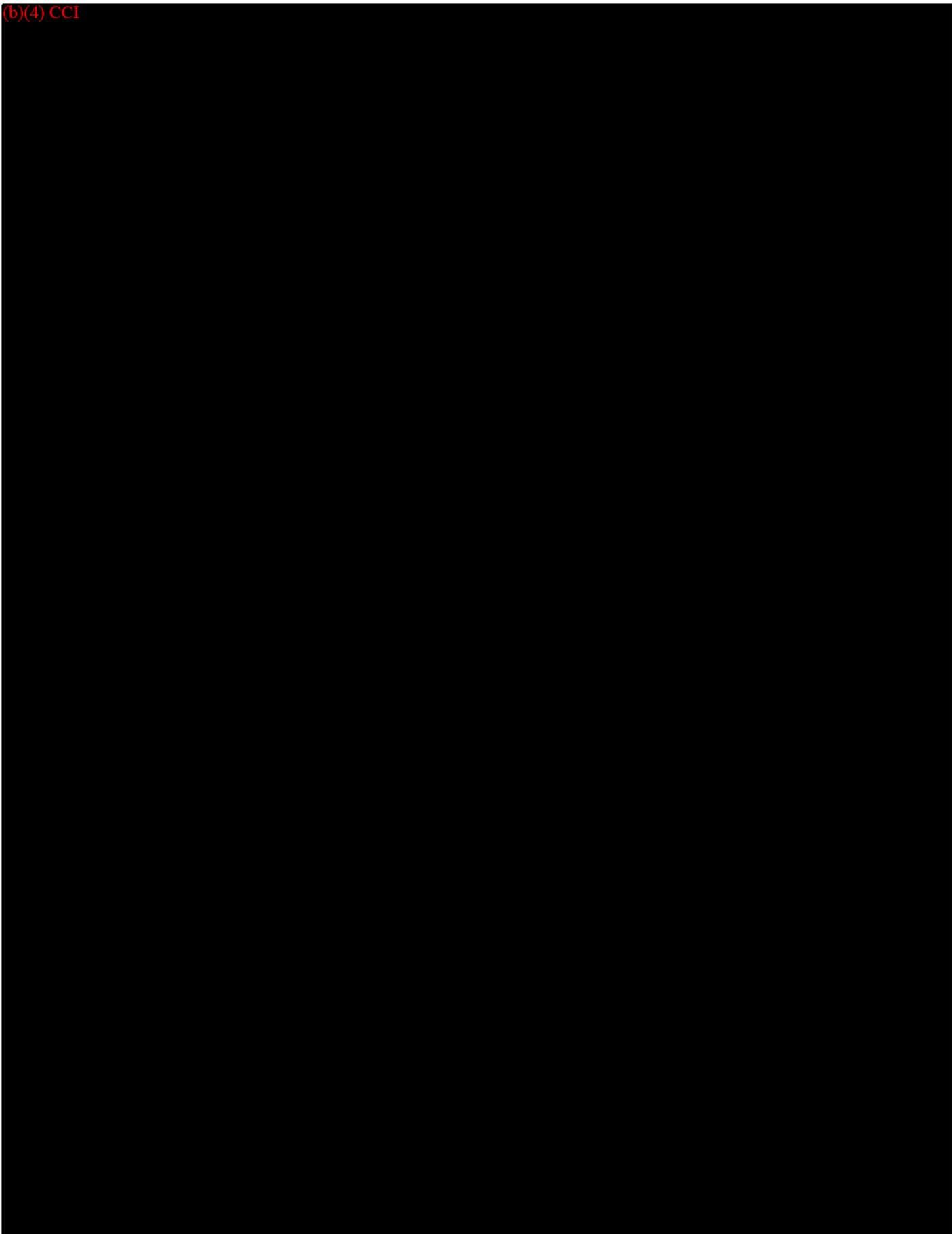
TREATED							UNTREATED					
	Baseline	Day 1			Day 5		D					
140	1	1	1	1	1	1	D	1	1	1	1	0
	2	1	2	3	3	2	E	1	1	1	1	1
	3	1	1	1	1	1	A	1	1	1	1	1
142	1	2	3	2	1	1	A	2	2	2	2	2
	2	1	1	0	0	0	B	1	2	2	2	2
	3	2	2	2	1	1	C	2	1	1	1	1
	4	3	3	2	1	1	D	2	1	1	1	1
	5	1	1	2	1	1	E	1	1	1	1	1
							F	1	1	1	1	1
144	1	2	1	1	1	1	B	1	3	2	2	2
	2	3	2	3	2	2	D	1	1	1	1	1
	3	1	1	0	0	0	E	1	1	2	2	1
	4	2	2	2	2	3	F	1	2	1	1	1
	5	2	3	2	1	1						
	6	1	2	2	1	0						
	7	3	3	3	3	2						

NoNo Study

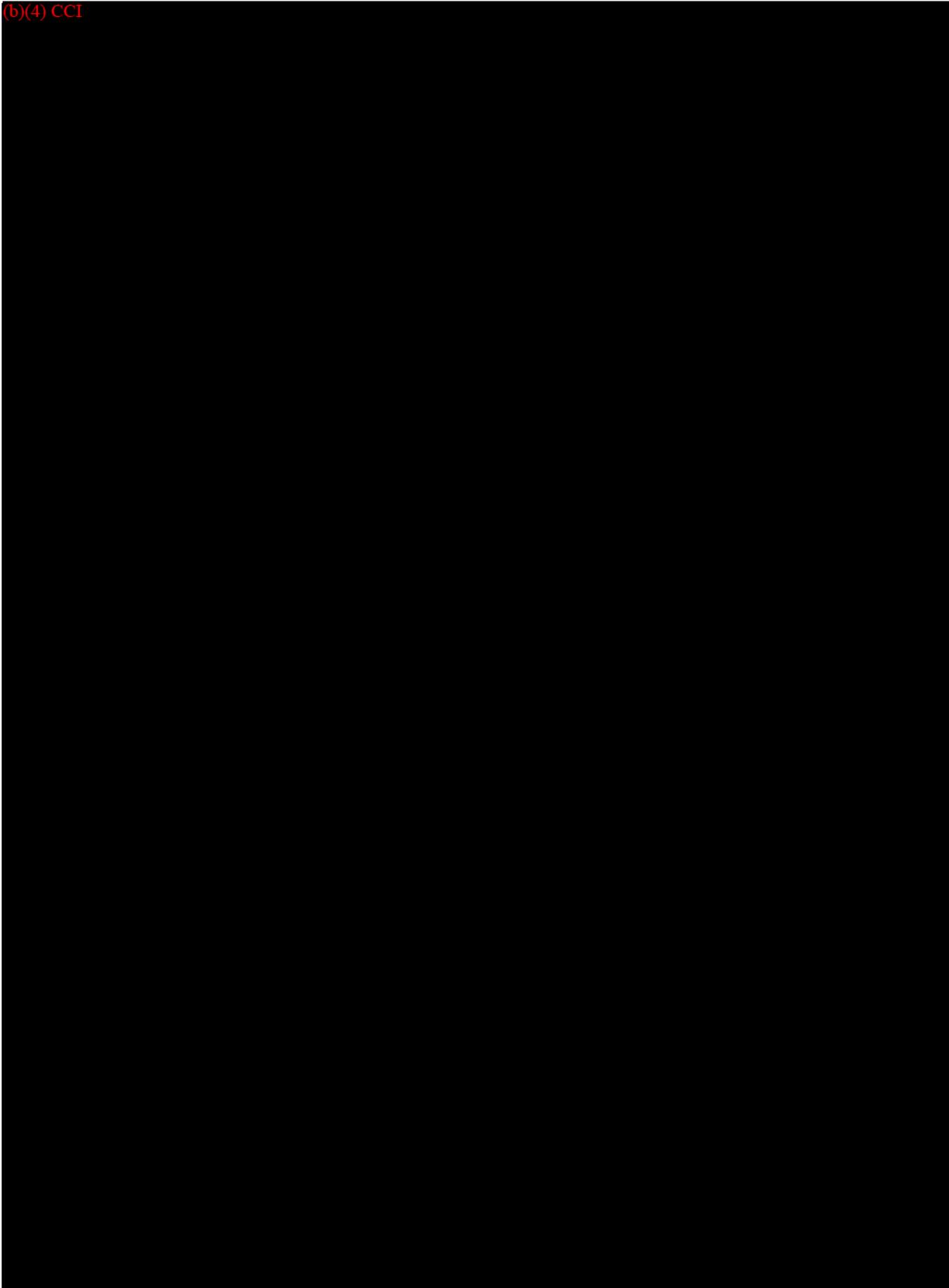
(b)(4) CCI



(b)(4) CCI



(b)(4) CCI



The reviewer's response to these data was:

(b)(4) CCI
[Redacted]

As a result, the sponsor was sent an October 21, 2008, request for additional information with the following deficiency:

(b)(4) CCI
[Redacted]

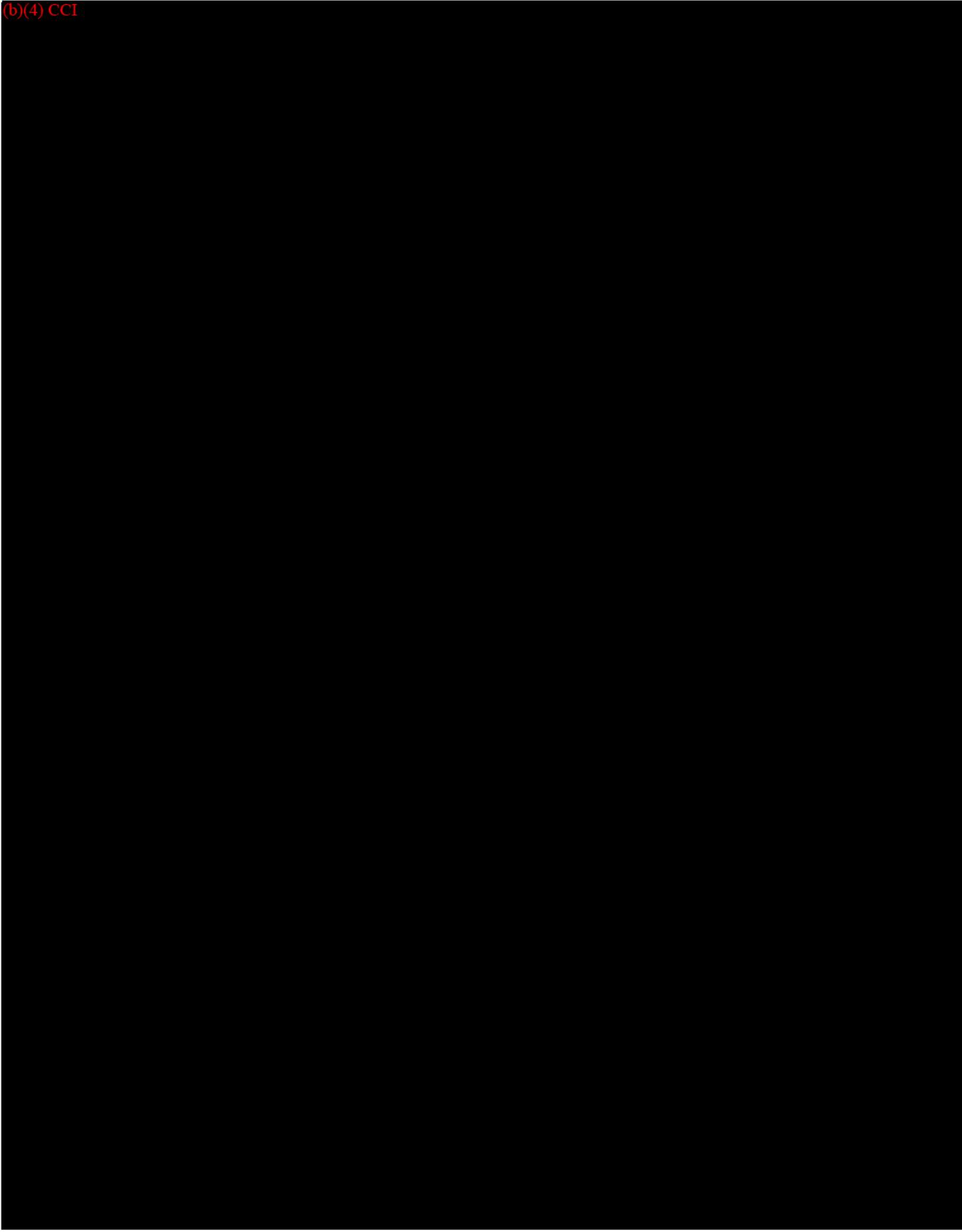
I would note that the sponsor

[Redacted] (b)(4) CCI [Redacted]

[Redacted]

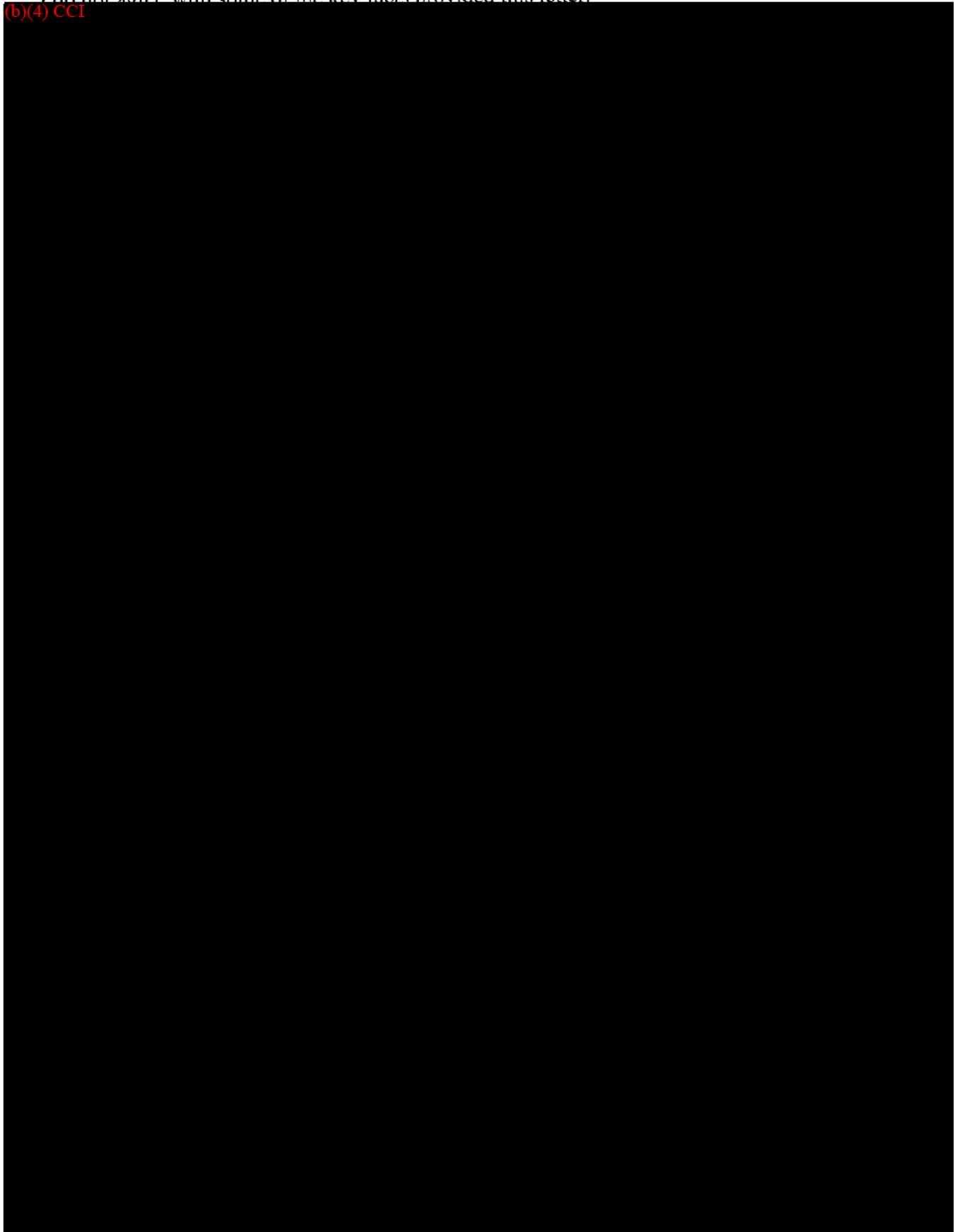
(b)(4) CCI
[Redacted]

(b)(4) CCI



I do not agree with some of the key facts provided this letter.

(b)(4) CCI



compare patient-outcomes across studies due to potential differences in patient characteristics and the time course of the natural progression of acne.

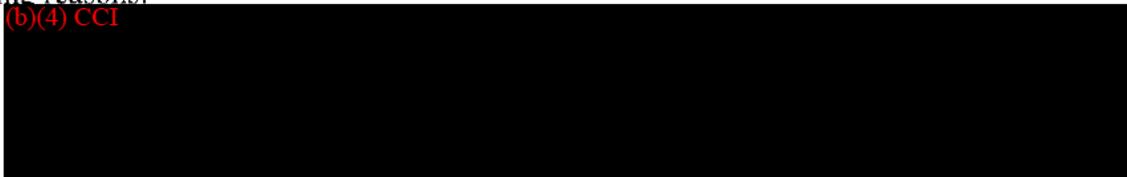
Decision

After carefully reviewing all the facts in this submission and in the predicate device submissions, meeting with the sponsor, meeting multiple times with the review team, and consulting with Dr. Luke, I believe that the results of the NoNo clinical study are sufficient to demonstrate that the device has equivalent effectiveness for the purposes of demonstrating substantial equivalence.

I met with the division on June 25, 2009, to share my draft memo and present my conclusions. In attendance were Mark Melkerson (division director), Neil Ogden (branch chief), Kareem Burney (reviewer), Markham Luke (ODE clinical deputy) and Cindy Demian (POS). The reviewer noted that the primary basis for his NSE recommendation was the fact that the percentage of patients who had resolution with the NoNo device was much lower than with the predicate Zeno device. When I asked about the Thermaclear device, I was informed that it was not used for comparison, because the technology of the NoNo device was more similar to the Zeno device. I note that all three devices have the identical indications.

I noted that it is appropriate to try to directly compare clinical study results, for the following reasons:

1. (b)(4) CCI



2. The results for the control patients in the various studies were clearly different, further suggesting that there were differences in the patient populations.

Percent Resolved/Almost resolved at Day 5

	Treated	Control
Zeno	100%	77%
NoNo	70%	56%
Thermaclear	38%	17%

3. The scoring methodologies were different in the two studies. The Zeno study used a 4-point scale (resolved, improved, no difference, worse) while the NoNo study used a 5-point scale, that also included "almost resolved". The Thermaclear study also used a 4-point scale.

Following the meeting, I emailed a draft of my review memo to the review team and division and asked for written comments by July 2. I received no comments, and so finalized this memo, and requested that POS prepare a letter responding to the appeal,

stating that I am overturning the NSE decision from the division, as well as a SE letter with my signature block. The appeal letter should include the following language as the basis for my decision:

You have provided data from a double-blinded, randomized controlled clinical trial that demonstrate that your device provides a statistically and clinically significant improvement in the time to improvement and time to resolution of mild to moderate acne as assessed by blinded investigators. I have determined based on these data that your device has performance that is substantially equivalent to predicate devices cleared for over-the-counter used in the treatment of mild to moderate acne.

Demian, Cindy

From: Melkerson, Mark N.
Sent: Tuesday, July 07, 2009 9:15 PM
To: Tillman, Donna-Bea; Demian, Cindy
Cc: Rosecrans, Heather S.
Subject: Re: Appeal letter - NoNo

DBT, I read the letter and have found no factual errors. MNM

From: Tillman, Donna-Bea
To: Melkerson, Mark N.; Demian, Cindy
Cc: Rosecrans, Heather S.
Sent: Tue Jul 07 12:29:26 2009
Subject: Appeal letter - NoNo

I have taken most of Heather's changes, and made a few more of my own.
<<K082423- No No Skin-Overturn NSE to SE- Appeal Letter- draft v2.DOC>>

Mark: Since I am overturning your prior decision, it is not necessary for you to concur. However, I would ask that you send me an email by COB today (and cc: Cindy) indicating that you have seen this letter and that it contains no factual errors.

Cindy: Once Mark has responded, we can put both of the letters in final for my signature tomorrow.

Donna-Bea

From: Rosecrans, Heather S.
Sent: Tuesday, July 07, 2009 11:50 AM
To: Tillman, Donna-Bea; Luke, Markham C; Melkerson, Mark N.; Demian, Cindy
Subject: K082423- No No Skin-Overturn NSE to SE- Appeal Letter- draft v 1.DOC

Hi,
Please see my suggested edits. Thx.
Heather

<< File: K082423- No No Skin-Overturn NSE to SE- Appeal Letter- draft v 1.DOC >>

7/8/2009

Demian, Cindy

From: Rosecrans, Heather S.
Sent: Tuesday, July 07, 2009 11:50 AM
To: Tillman, Donna-Bea; Luke, Markham C; Melkerson, Mark N.; Demian, Cindy
Subject: K082423- No No Skin-Overturn NSE to SE- Appeal Letter- draft v 1.DOC

Attachments: K082423- No No Skin-Overturn NSE to SE- Appeal Letter- draft v 1.DOC

Hi,
Please see my suggested edits. Thx.
Heather



K082423- No No
skin-Overturn N..

Radiancy (Israel) LTD.
c/o Boston MedTech Advisors, Inc.
Zvi Ladin, PhD, Principal
990 Washington Street, Suite 204
Dedham, MA 02026

Re: k082423
No! No! Skin™
Appeal of Not Substantially Equivalent Decision
Dated: December 18, 2008
Received: December 19, 2008

Dear Dr. Ladin:

This letter is in response to your letter of appeal dated December 18, 2008, requesting that the not substantially equivalent (NSE) decision for the above reference premarket notification submission (510(k)) that was issued on December 3, 2008, from Mark N. Melkerson, Director, Division of General, Restorative, and Neurological Devices (DGRND), now the Division of Surgical, Orthopedic, and Restorative Devices (DSORD), Office of Device Evaluation, be reviewed by the next level supervisor. I have reviewed this appeal under our regulations found in Title 21 of the Code of Federal Regulations Part 10.75 Internal agency review of decision, as the next level supervisor.

After reviewing your letter of appeal, including my review of the 510(k), meeting internally on several occasions with DSORD, and discussing your appeal with you and your clients on February 17, 2009, and consulting with my deputy... Markam???. I have determined that your device has performance that is substantially equivalent to predicate devices cleared for over-the-counter used in the treatment of mild to moderate acne. My decision is based on the fact that your 510(k) contained data from a double-blinded, randomized controlled clinical trial that I believe demonstrates that your device provides a statistically and clinically significant improvement in the time to improvement and time to resolution of mild to moderate acne as assessed by blinded investigators over no treatment ??? in order to provide reasonable assurance of the safety and effectiveness of your device to be found substantially equivalent. Therefore, I am overturning the NSE decision from DSORD and issuing a letter of substantial equivalence (enclosed) for the above reference device as described in the 510(k).

Deleted: re

Deleted: considered the NSE decision.

Deleted: have provided

Deleted: I have determined based on these data that

Deleted: your device has performance that is substantially equivalent to predicate devices cleared for over-the-counter used in the treatment of mild to moderate acne.

If you have any questions regarding this letter, please contact Heather S. Rosecrans, Chief, 510(k) Staff at (240) 276- 4021.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.

Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Demian, Cindy

From: Demian, Cindy
Sent: Tuesday, July 07, 2009 2:21 PM
To: Rosecrans, Heather S.
Cc: Tillman, Donna-Bea; Melkerson, Mark N.; Luke, Markham C; Ogden, Neil; Burney, Kareem
Subject: RE: K082423-SE Letter .DOC
Attachments: RE: K082423-SE Letter .DOC; K082423-SE Letter v 1.DOC

Attached is the revised SE letter.

From: Rosecrans, Heather S.
Sent: Tuesday, July 07, 2009 1:15 PM
To: Demian, Cindy
Cc: Tillman, Donna-Bea; Melkerson, Mark N.; Luke, Markham C; Ogden, Neil; Burney, Kareem
Subject: K082423-SE Letter .DOC

Hi Cindy,
Please use the last dates of the 510(k) submission itself on the SE letter. Also, please be sure to have DSMICA's new phone number. Thx.

<< File: K082423-SE Letter .DOC >>

Demian, Cindy

From: Rosecrans, Heather S.
Sent: Tuesday, July 07, 2009 2:19 PM
To: Demian, Cindy
Subject: RE: K082423-SE Letter .DOC

Yes, please

Heather

Main Line (240) 276-4040
Direct Line (240) 276-4021
Fax (240) 276-4009
Heather.Rosecrans@FDA.HHS.gov

From: Demian, Cindy
Sent: Tuesday, July 07, 2009 1:44 PM
To: Rosecrans, Heather S.
Subject: RE: K082423-SE Letter .DOC

Heather,

The last date that is in the system is December 3, 2008, which is the date the NSE letter was issued to the sponsor. The submission was received on October 24 2008, the letter was dated October 23, and an NSE letter was issued on December 3, 2008.

"The last dates of the submission itself," do you mean that you want me to use the last supplement dates, which would mean using the October 23, 2008 date?

Per your request below, I updated DSMICA's new phone number. FYI, I used the SE boilerplate letter from the eRoom this morning, which should have had this new information.

I have attached the revised SE letter for your convenience,

Cindy

<< File: K082423-SE Letter v 1.DOC >>

From: Rosecrans, Heather S.
Sent: Tuesday, July 07, 2009 1:15 PM
To: Demian, Cindy
Cc: Tillman, Donna-Bea; Melkerson, Mark N.; Luke, Markham C; Ogden, Neil; Burney, Kareem
Subject: K082423-SE Letter .DOC

Hi Cindy,

Please use the last dates of the 510(k) submission itself on the SE letter. Also, please be sure to have DSMICA's new phone number. Thx.

25

<< File: K082423-SE Letter .DOC >>

Demian, Cindy

From: Demian, Cindy
Sent: Tuesday, July 07, 2009 1:44 PM
To: Rosecrans, Heather S.
Subject: RE: K082423-SE Letter .DOC

Attachments: K082423-SE Letter v 1.DOC

Heather,

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“The last dates of the submission itself,” do you mean that you want me to use the last supplement dates, which would mean using the October 23, 2008 date?

Per your request below, I updated DSMICA's new phone number. FYI, I used the SE boilerplate letter from the eRoom this morning, which should have had this new information.

I have attached the revised SE letter for your convenience,

Cindy



K082423-SE
Letter v 1.DOC (59

From: Rosecrans, Heather S.
Sent: Tuesday, July 07, 2009 1:15 PM
To: Demian, Cindy
Cc: Tillman, Donna-Bea; Melkerson, Mark N.; Luke, Markham C; Ogden, Neil; Burney, Kareem
Subject: K082423-SE Letter .DOC

Hi Cindy,
Please use the last dates of the 510(k) submission itself on the SE letter. Also, please be sure to have DSMICA's new phone number. Thx.

<< File: K082423-SE Letter .DOC >>

Radiancy (Israel) LTD.
c/o Boston MedTech Advisors, Inc.
Zvi Ladin, PhD, Principal
990 Washington Street, Suite 204
Dedham, MA 02026

Re: k082423

Trade/Device Name: No! No! Skin™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in
Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 23, 2008
Received: October 24, 2008

Dear Dr. Ladin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k082423

Device Name: No! No! Skin™

Indications For Use: No! No! Skin is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

The product code is: GEX

Regulation number: 21 CFR 878.4810

Regulation name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory class: II

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _____

(Please include 510(k) number here: K.)

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date

cc: HFZ-401 DMC
 HFZ-404 510(k) Staff
 HFZ- Division
 D.O.

Boilerplate Last Updated: 6/18/09 – Brandi Stuart

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Demian, Cindy

From: Rosecrans, Heather S.
Sent: Tuesday, July 07, 2009 12:26 PM
To: Tillman, Donna-Bea; Burney, Kareem; Demian, Cindy; Melkerson, Mark N.; Ogden, Neil; Luke, Markham C; Shulman, Marjorie G.; Stuart, Julie (Brandi)
Subject: RE: Final NoNo memo- K082423

Ok, that sounds like a good strategy.

Brandi,

Please work with the division to obtain a new product code for these type acne devices and issue corrected SE letters for all of them by the end of Aug. Thx.

Heather

Main Line (240) 276-4040
Direct Line (240) 276-4021
Fax (240) 276-4009
Heather.Rosecrans@FDA.HHS.gov

From: Tillman, Donna-Bea
Sent: Tuesday, July 07, 2009 12:14 PM
To: Rosecrans, Heather S.; Burney, Kareem; Demian, Cindy; Melkerson, Mark N.; Ogden, Neil; Luke, Markham C; Shulman, Marjorie G.; Stuart, Julie (Brandi)
Subject: RE: Final NoNo memo- K082423

All of the predicates were GEX. I'd prefer to make this one be GEX too, and then if we want to do a procode cleanup at a later date, do that.

Donna-Bea

From: Rosecrans, Heather S.
Sent: Tuesday, July 07, 2009 11:55 AM
To: Burney, Kareem; Demian, Cindy; Tillman, Donna-Bea; Melkerson, Mark N.; Ogden, Neil; Luke, Markham C; Shulman, Marjorie G.; Stuart, Julie (Brandi)
Subject: RE: Final NoNo memo- K082423

Thx, Kareem. We will need the indications for use from the file for the SE letter. I think we need a new product code for this one and would then need corrected letters for the predicates to fix the product code. Does DSORD disagree with the new code. I hate to put this into GEX.

Heather

Main Line (240) 276-4040
Direct Line (240) 276-4021

Fax (240) 276-4009
Heather.Rosecrans@FDA.HHS.gov

From: Burney, Kareem
Sent: Tuesday, July 07, 2009 11:53 AM
To: Demian, Cindy; Tillman, Donna-Bea; Melkerson, Mark N.; Ogden, Neil; Rosecrans, Heather S.; Luke, Markham C
Subject: RE: Final NoNo memo- K082423

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The product code is: GEX
Regulation number: 21 CFR 878.4810
Regulation name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory class: II

Kareem

From: Demian, Cindy
Sent: Tuesday, July 07, 2009 11:22 AM
To: Tillman, Donna-Bea; Melkerson, Mark N.; Ogden, Neil; Burney, Kareem; Rosecrans, Heather S.; Luke, Markham C
Subject: RE: Final NoNo memo- K082423

Donna-Bea,

Per your request, I have prepared both draft letters: 1) the appeal letter overturning the division's decision and the 2) SE letter. The division will have to provide the information for the indications for use and product code information. Please let me know if further assistance.

Thank you,

Cindy
<< File: K082423- No No Skin-Overturn NSE to SE- Appeal Letter- draft v 1.DOC >> << File: K082423-SE Letter .DOC >>

From: Tillman, Donna-Bea
Sent: Tuesday, July 07, 2009 9:21 AM
To: Melkerson, Mark N.; Ogden, Neil; Burney, Kareem; Demian, Cindy; Rosecrans, Heather S.; Luke, Markham C
Subject: Final NoNo memo

I am attaching the final version of my decision on the NoNo appeal.
<< File: DBT NoNo Appeal memo final.doc >>

Cindy: Please prepare a draft letter responding to the appeal that includes the language I have provided at the end of my memo. I will also need a SE letter with my signature block. I'd like to get this signed tomorrow.

34

Thanks.

Donna-Bea

Donna-Bea Tillman, Ph.D.
Director, Office of Device Evaluation
FDA/CDRH
9200 Corporate Blvd, HFZ-400
Rockville, MD 20850
240-276-3993
donna-bea.tillman@fda.hhs.gov

35

Demian, Cindy

From: Demian, Cindy
Sent: Tuesday, July 07, 2009 12:24 PM
To: Tillman, Donna-Bea; Rosecrans, Heather S.; Burney, Kareem; Melkerson, Mark N.; Ogden, Neil; Luke, Markham C; Shulman, Marjorie G.; Stuart, Julie (Brandi)
Subject: RE: Final NoNo memo- K082423
Attachments: K082423-SE Letter v 1.DOC

Based on Donna-Bea's email below, I have updated the SE letter to include GEX procode information, etc.

Cindy



K082423-SE
Letter v 1.DOC (59)

From: Tillman, Donna-Bea
Sent: Tuesday, July 07, 2009 12:14 PM
To: Rosecrans, Heather S.; Burney, Kareem; Demian, Cindy; Melkerson, Mark N.; Ogden, Neil; Luke, Markham C; Shulman, Marjorie G.; Stuart, Julie (Brandi)
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Donna-Bea

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Attachments: K082423- No No Skin-Overturn NSE to SE- Appeal Letter- draft v 1.DOC;
K082423-SE Letter .DOC

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Donna-Bea

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Subject: RE: Final NoNo memo- K082423

Attachments: K082423- No No Skin-Overturn NSE to SE- Appeal Letter- draft v 1.DOC;
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Cindy



K082423- No No K082423-SE
skin-Overturn N...ter .DOC (59 KB)

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Donna-Bea Tillman, Ph.D.
Director, Office of Device Evaluation
FDA/CDRH
9200 Corporate Blvd, HFZ-400
Rockville, MD 20850
240-276-3993
donna-bea.tillman@fda.hhs.gov

Demian, Cindy

From: Demian, Cindy
nt: Tuesday, July 07, 2009 11:23 AM
Subject: RE: Final NoNo memo

Yes, I was working on both letters that you requested.

-----Original Message-----

From: Tillman, Donna-Bea
Sent: Tuesday, July 07, 2009 11:21 AM
To: Demian, Cindy
Subject: RE: Final NoNo memo

Cindy:

Just checking in to make sure you saw the email I sent you earlier...

Donna-Bea

-----Original Message-----

From: Demian, Cindy
Sent: Tuesday, July 07, 2009 9:21 AM
To: Tillman, Donna-Bea
Subject: Out of Office AutoReply: Final NoNo memo

July 7, 2009- I am currently working from my alternative worksite will be available until 3:30 pm. Please feel free to email leave a voice mail message and I will respond to your concerns promptly. Thank you.

Demian, Cindy

From: Tillman, Donna-Bea
Sent: Tuesday, July 07, 2009 9:21 AM
To: Melkerson, Mark N.; Ogden, Neil; Burney, Kareem; Demian, Cindy; Rosecrans, Heather S.; Luke, Markham C
Subject: Final NoNo memo

Attachments: DBT NoNo Appeal memo final.doc

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DBT NoNo
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Rockville, MD 20850
240-276-3993
donna-bea.tillman@fda.hhs.gov

Review of Request for Supervisory Review

Date: July 7, 2009

From: Donna-Bea Tillman, Ph.D, M.P.A
Director, Office of Device Evaluation

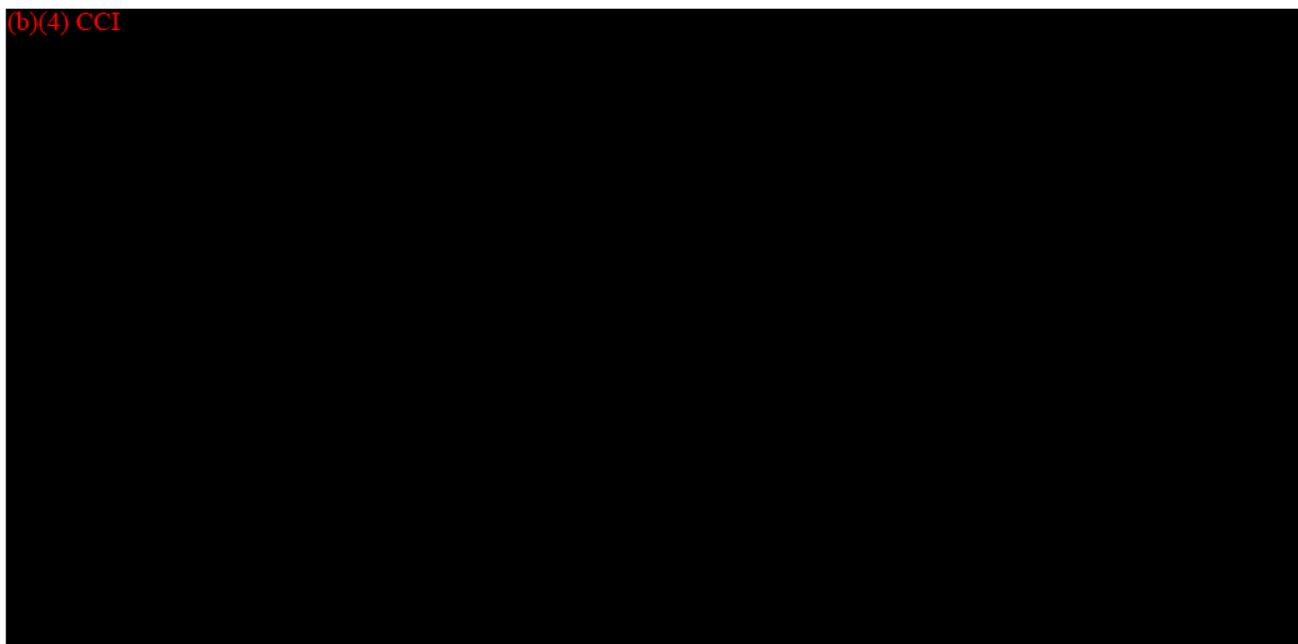
Re: Appeal of K082423, Radiancy No!No! device for the treatment of acne
NSE letter dated December 3, 2008

Action: Reverse NSE and issue SE letter

Background

The Radiancy No!No! (NoNo) is a battery-powered, handheld device indicated for the OTC treatment of individual lesions in mild to moderate inflammatory acne. The device uses a halogen lamp to deliver energy in the 450-2000nm wavelength range to a 50 mm² spot. Treatment time is 10 seconds, and the user is instructed to apply two treatments to each lesion twice a day.

(b)(4) CCI



Review Analysis

Predicate Devices

There are two predicate devices (both with OTC indications) that are the most relevant to this submission: the Tyrell “Zeno”, and the DermaCare “Thermaclear”. I will begin by summarizing the basis for the clearance of each of these devices.

1. Tyrell Zeno (K043377). Reviewer: Richard Felten. There was not a clinical review of this 510k. SE letter issued 6/1/2005.

The Zeno device uses low level heat (119 degF) to treat individual lesions in mild to moderate inflammatory acne. The device is battery powered, and treats a 71 mm² spot size. Treatment is 2.5 minutes per lesion, and the treatment paradigm is two treatments on the first day, and one treatment on the second. This was the first “heat-based” device to treat acne (predicates were low-level light devices).

The study was a double-blinded, randomized controlled trial of 51 subjects with mild to moderate acne. Of note (and as opposed to the NoNo device), subjects with pustular acne were excluded. The investigator selected two comparable blemishes, and one was treated with the Zeno device, the other was treated with a placebo device (Note: The placebo device only achieved a temperature of 94 degF, while the Zeno device reached 119 degF). Photographs of each blemish were taken at each follow-up visit.

Patients maintained a patient diary in which they recorded an assessment of each blemish on each day. The four types of responses were: resolved, improved, no improvement, or worsened. The first day that a blemish was rated as resolved was used to determine the time to resolution. The time to resolution was the pre-specified primary endpoint for the study. Secondary efficacy endpoints included the blinded investigator’s assessment of the treated area. Adverse events were also recorded.

The primary endpoint of the study was met. The median time to resolution for the Zeno device (in hours, and as reported in the patient diary) was 90 (95% CI [69, 118]) as compared to 140 [119, 166], with a $p < 0.0020$ (log-rank test). The percentage of blemishes that resolved or improved, as assessed by the blinded investigator, was also significantly better for the Zeno device (100% for the Zeno device, and 77% for the control at day 5).

It appears from the record that the reviewer primarily relied on the blinded investigator assessment of the percentage of lesions improved or resolved by day 5, and that these results are comparable to those observed for other devices previously cleared for the treatment of facial acne.

2. Dermacare Thermaclear (K060653). Reviewer: Richard Felten. There was not a clinical review of this 510k.

The Thermaclear device uses a nichrome heating element to apply thermal energy to a 127 mm² spot to treat individual pimples in mild to moderate inflammatory acne. Peak temperatures at the skin is 150 degF, and the duration of treatment is 2 sec.

The study included 43 patients with 278 treated lesions. However, because control lesions were not assessed for all of these patients, the review focused on 14 subjects who had 53 lesions treated and 51 control lesions. [Note: In this study, the control lesions did not receive any treatment] Lesions were evaluated by baseline, and on a daily basis out to five days. Assessments were made by a blinded investigator based on a review of photographs. A severity scale of 0-3 was used, with 0 being a non-inflamed lesion, and 3 being a severe visible lesion raised 2mm or more above the skin with erythema extended greater than 1mm. Although not explicitly stated, it appears that the primary endpoint was lesion score at day 5.

At day five, the average lesion score was 0.83 for the treatment group (baseline 1.58) and 1.18 for the control group (baseline 1.62). The reviewer notes that “even non-treated lesions improve over time...however, the treated lesions show a greater degree of improvement”.

A second analysis was performed looking at lesion response, where a severity score of 0 represents “resolved”, and a day 5 score that is lower than baseline represents “improvement”.

	Treated group	Control group
Resolved	38%	17%
Improved	26%	29%
Resolved/Improved	64%	46%

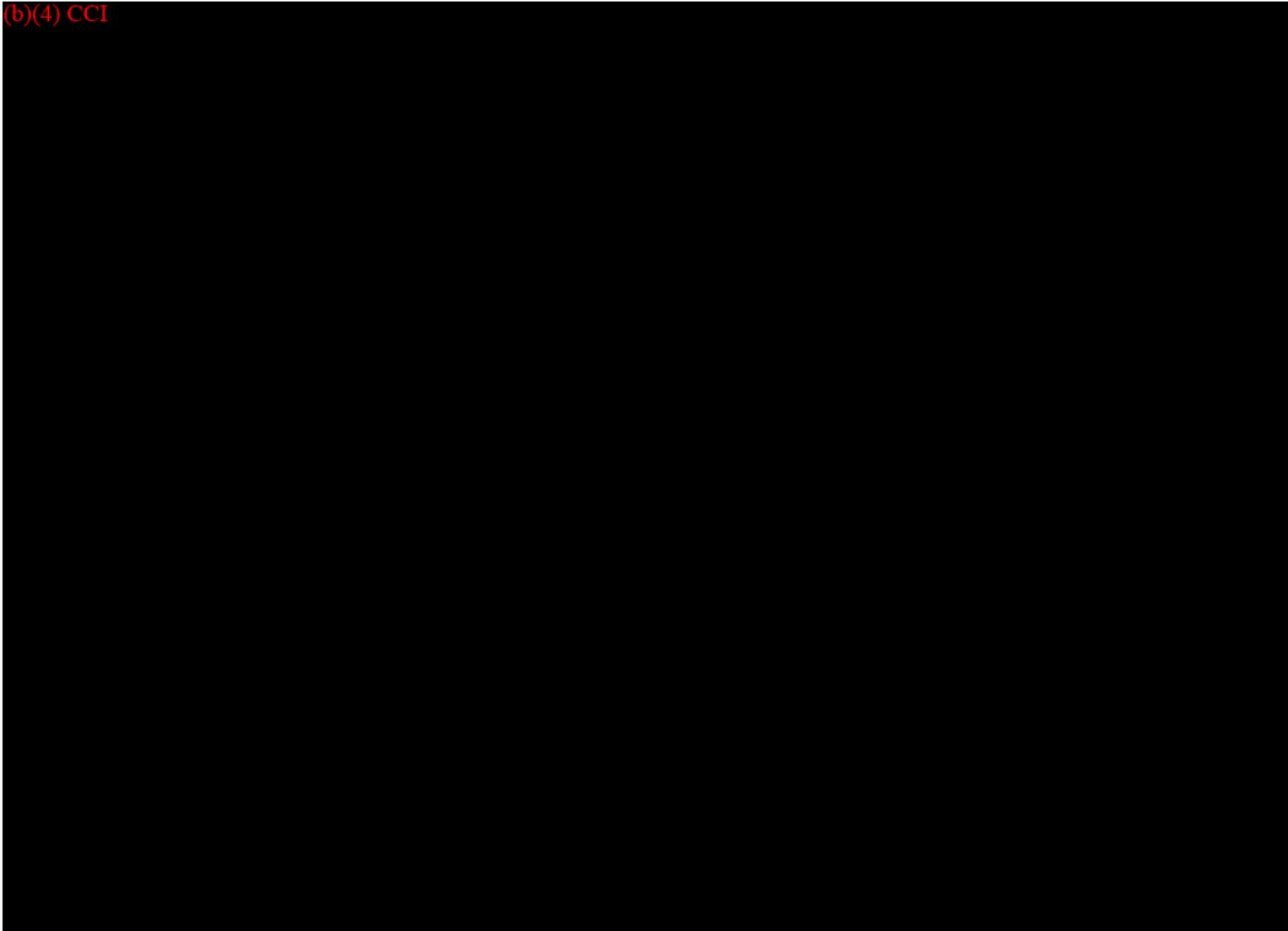
The reviewer notes that “Again this indicates that treatment does provide benefit with a greater number of lesions in the treated group having a score of 0 [resolved] by day 5”. The reviewer goes on to note that: “In terms of comparison to the predicate device, the Zeno device, both of these devices essentially reduce the time to clearance of acne lesions. The endpoint for the Zeno study was time to clearance with the treated lesion demonstrating a quicker time to clearance”.

Note: Although not explicitly mentioned by the reviewer, the data table provided by the firm (IMAGE p.21) shows that even in the treated arm, some subjects have a severity score at day 5 that is greater than the score at baseline (e.g., patient 140 has a lesion that is rated “1” at baseline at “2” at day 5, and patient 144 has a lesion that is “2” at baseline and “3” at day 5). In other words, some of the treated patient get worse. This will be important in considering the NoNo results.

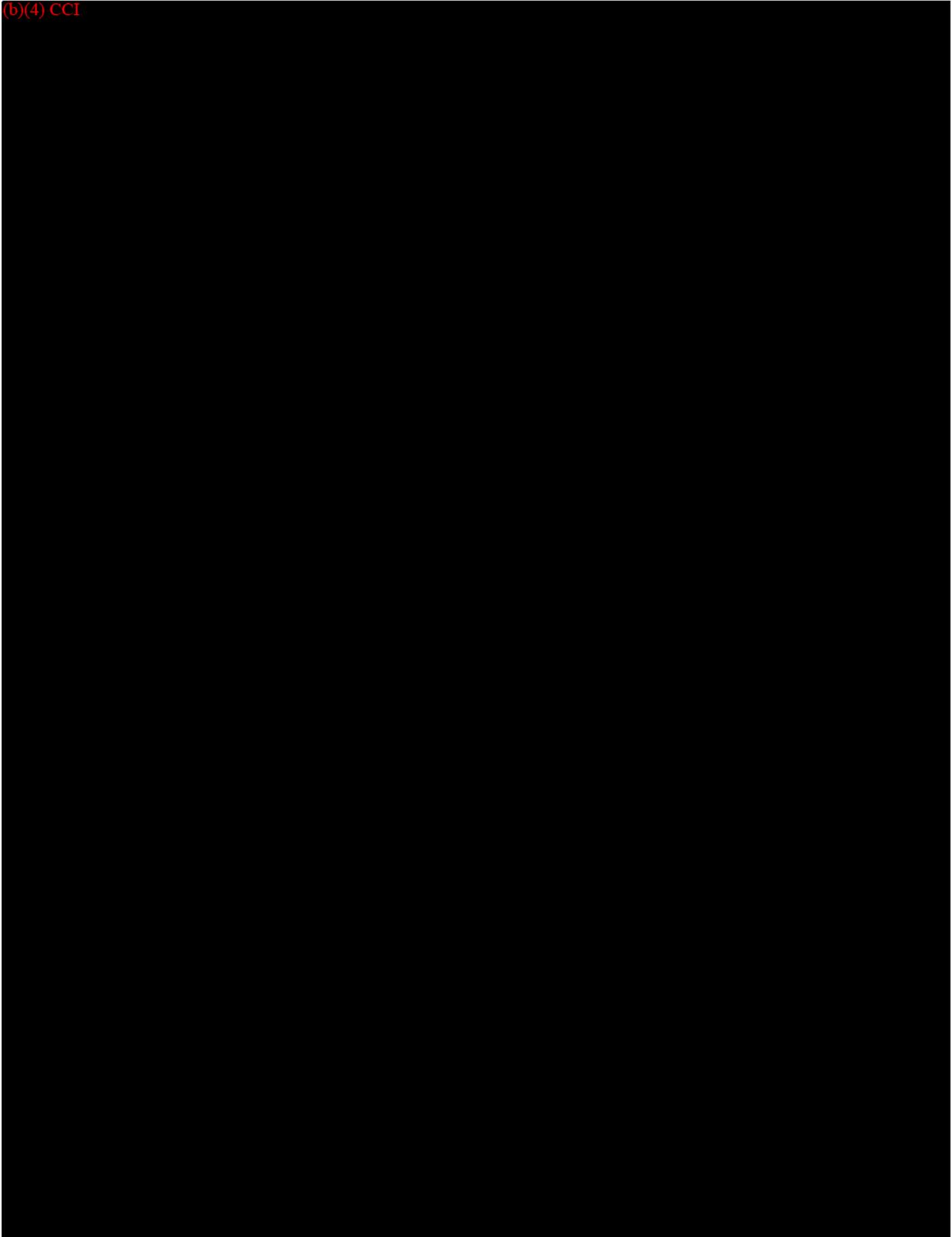
TREATED							UNTREATED					
	Baseline	Day 1				Day 5						
140	1	1	1	1	1	1	D	1	1	1	1	0
	2	1	2	3	3	2	E	1	1	1	1	1
	3	1	1	1	1	1	A	1	1	1	1	1
142	1	2	3	2	1	1	A	2	2	2	2	2
	2	1	1	0	0	0	B	1	2	2	2	2
	3	2	2	2	1	1	C	2	1	1	1	1
	4	3	3	2	1	1	D	2	1	1	1	1
	5	1	1	2	1	1	E	1	1	1	1	1
144	1	2	1	1	1	1	F	1	1	1	1	1
	2	3	2	3	2	2	B	1	3	2	2	2
	3	1	1	0	0	0	D	1	1	1	1	1
	4	2	2	2	2	3	E	1	1	2	2	1
	5	2	3	2	1	1	F	1	2	1	1	1
	6	1	2	2	1	0						
	7	3	3	3	3	2						

NoNo Study

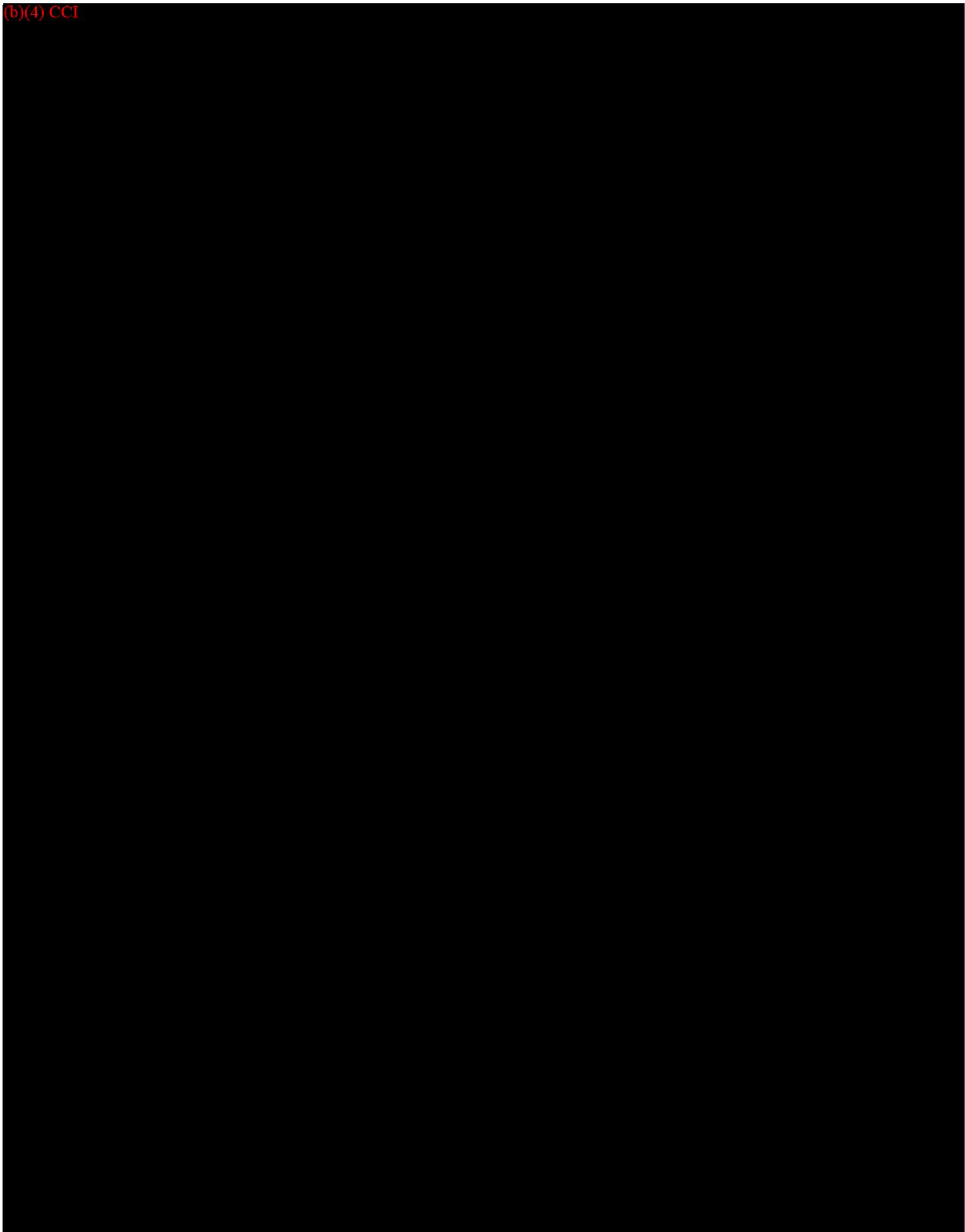
(b)(4) CCI



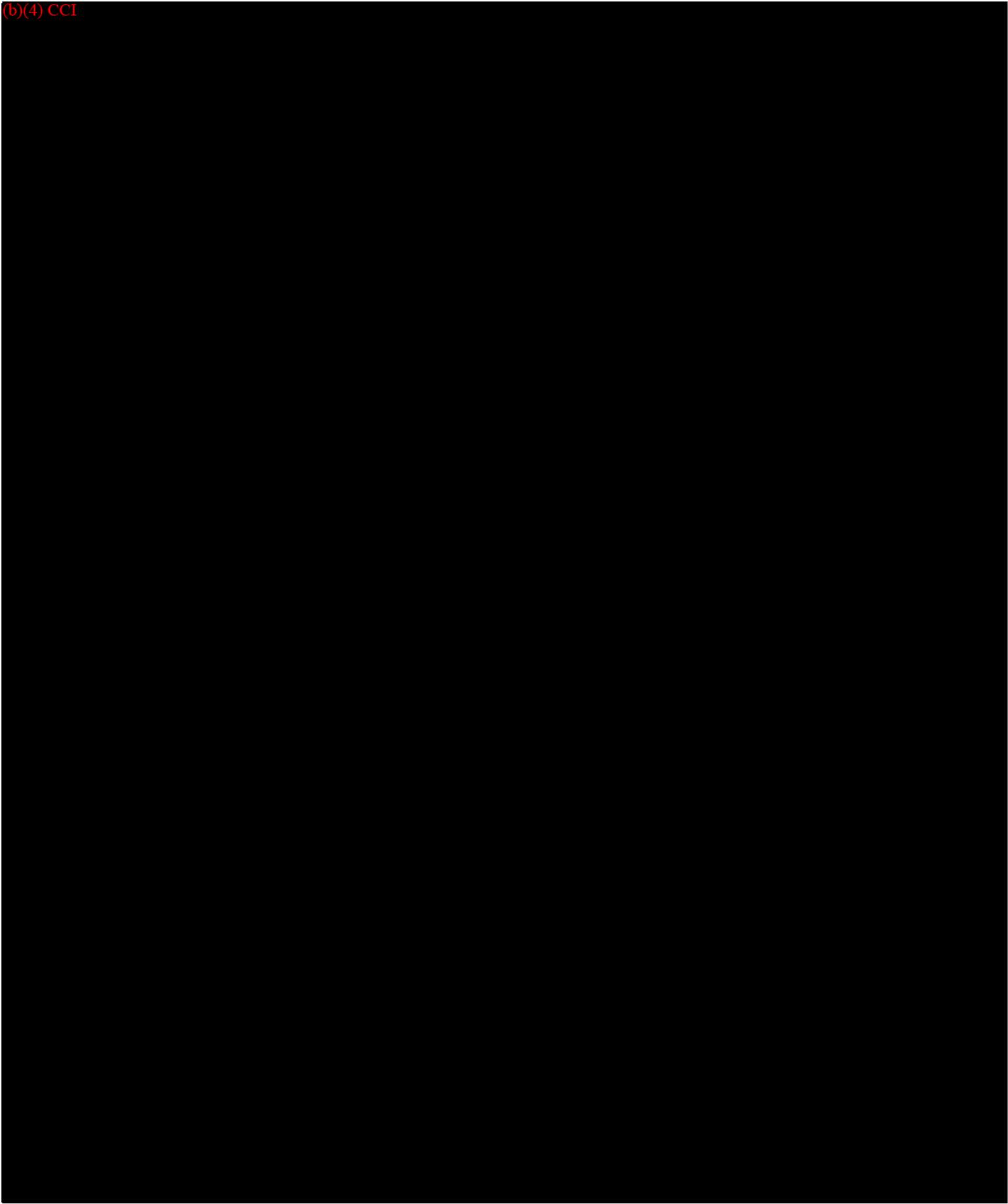
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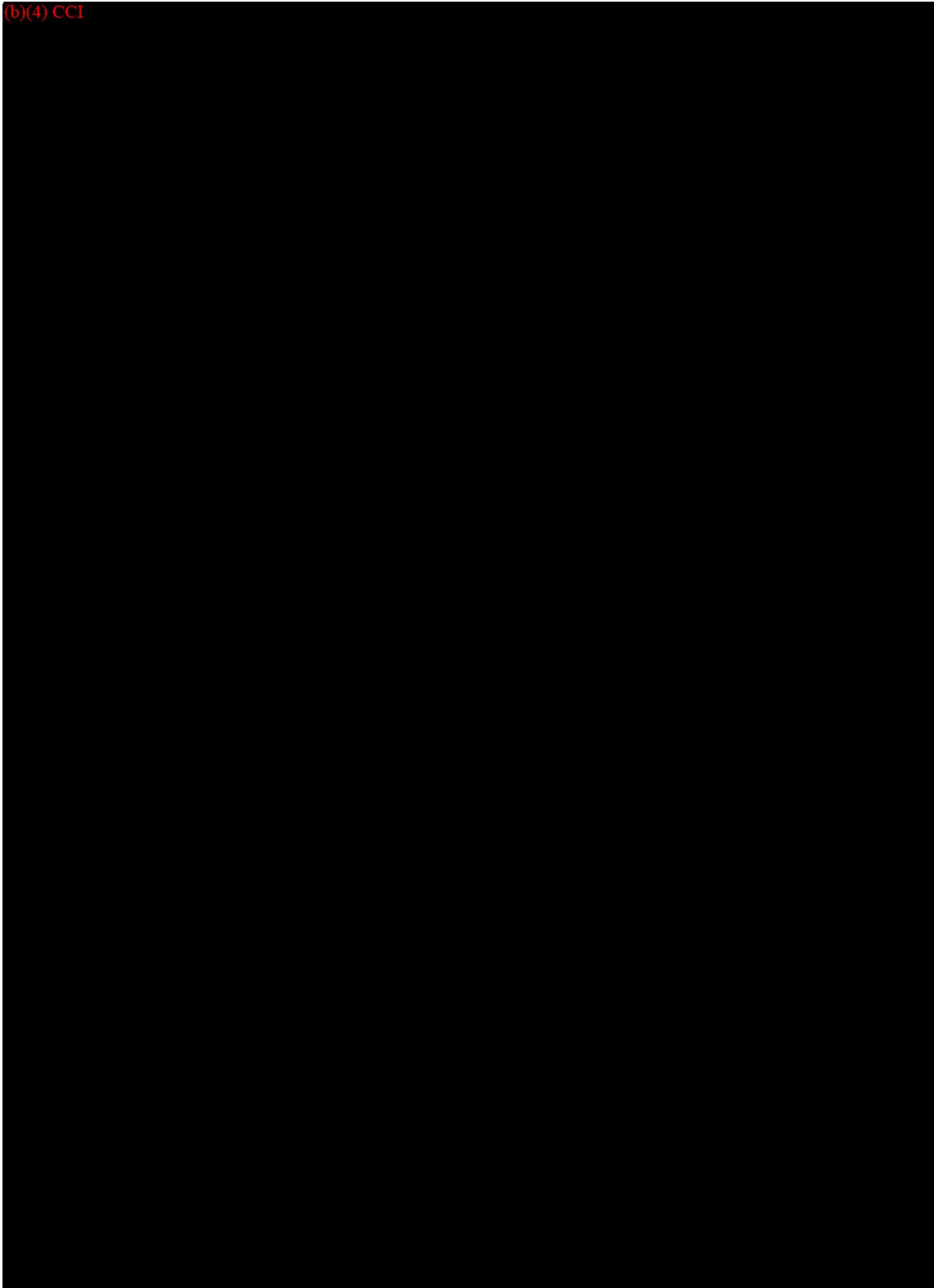
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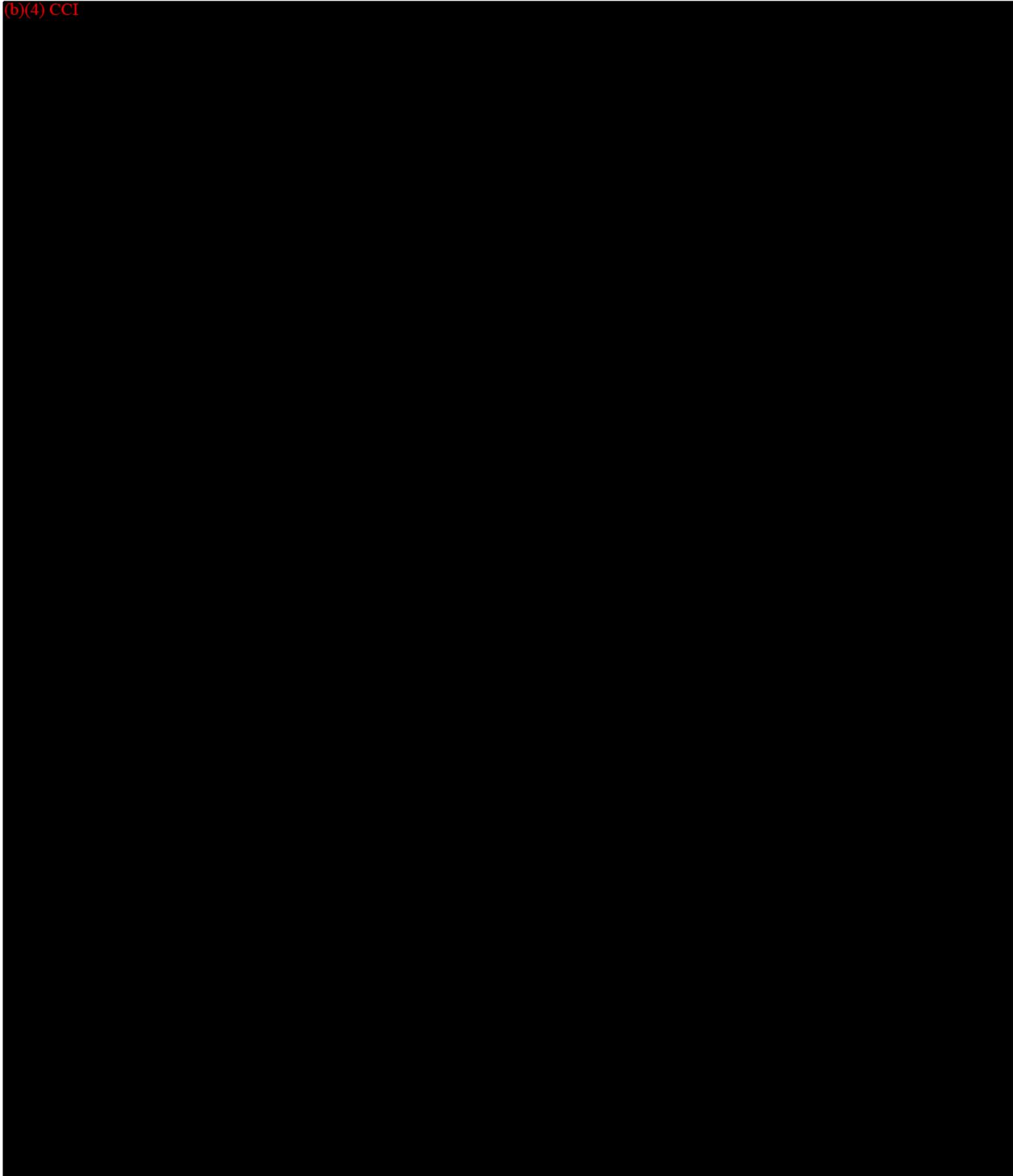
(b)(4) CCI



(b)(4) CCI



(b)(4) CCI



compare patient-outcomes across studies due to potential differences in patient characteristics and the time course of the natural progression of acne.

Decision

After carefully reviewing all the facts in this submission and in the predicate device submissions, meeting with the sponsor, meeting multiple times with the review team, and consulting with Dr. Luke, I believe that the results of the NoNo clinical study are sufficient to demonstrate that the device has equivalent effectiveness for the purposes of demonstrating substantial equivalence.

I met with the division on June 25, 2009, to share my draft memo and present my conclusions. In attendance were Mark Melkerson (division director), Neil Ogden (branch chief), Kareem Burney (reviewer), Markham Luke (ODE clinical deputy) and Cindy Demian (POS). The reviewer noted that the primary basis for his NSE recommendation was the fact that the percentage of patients who had resolution with the NoNo device was much lower than with the predicate Zeno device. When I asked about the Thermaclear device, I was informed that it was not used for comparison, because the technology of the NoNo device was more similar to the Zeno device. I note that all three devices have the identical indications.

I noted that it is appropriate to try to directly compare clinical study results, for the following reasons:

1. We don't know if the populations were comparable, and there are many known and unknown covariates that can impact on the progression of acne. I have already noted one example: The Zeno study excluded patients with pustular acne, while these patients were included in the NoNo study.
2. The results for the control patients in the various studies were clearly different, further suggesting that there were differences in the patient populations.

Percent Resolved/Almost resolved at Day 5

	Treated	Control
Zeno	100%	77%
NoNo	70%	56%
Thermaclear	38%	17%

3. The scoring methodologies were different in the two studies. The Zeno study used a 4-point scale (resolved, improved, no difference, worse) while the NoNo study used a 5-point scale, that also included "almost resolved". The Thermaclear study also used a 4-point scale.

Following the meeting, I emailed a draft of my review memo to the review team and division and asked for written comments by July 2. I received no comments, and so finalized this memo, and requested that POS prepare a letter responding to the appeal,

stating that I am overturning the NSE decision from the division, as well as a SE letter with my signature block. The appeal letter should include the following language as the basis for my decision:

You have provided data from a double-blinded, randomized controlled clinical trial that demonstrate that your device provides a statistically and clinically significant improvement in the time to improvement and time to resolution of mild to moderate acne as assessed by blinded investigators. I have determined based on these data that your device has performance that is substantially equivalent to predicate devices cleared for over-the-counter used in the treatment of mild to moderate acne.

Demian, Cindy

From: Tillman, Donna-Bea
Sent: Thursday, June 25, 2009 2:18 PM
To: Demian, Cindy
Subject: RE: K082423- No! No! Skin [Radiancy (Israel) Ltd] Appeal - Overturn of NSE Decision-DGRND- recvd 12/19/08
Attachments: DBT NoNo Appeal memo v4.doc

Cindy:

My draft memo is a "living document" - I continually update it to correct factual errors, typos and to reflect additional information and discussions. It is only this final version that should be included in the Administrative Record.

It was never my intent for you to feel excluded from this process. I am attaching my most recent draft, which I just completed and had planned to send to you along with the rest of the team. You will see that it was edited to add what happened at today's meeting.

Donna-Bea

From: Demian, Cindy
Sent: Thursday, June 25, 2009 1:39 PM
To: Tillman, Donna-Bea
Subject: K082423- No! No! Skin [Radiancy (Israel) Ltd] Appeal - Overturn of NSE Decision- DGRND- recvd 12/19/08

Donna-Bea,

At the end of today's appeal meeting for K082423- No! No! Skin, you took my copy of your appeal memorandum that was distributed at the meeting, however, you let everyone else at the meeting retain their copy. You told me that you "did not want this memo to go into the official records."

As you are well aware, it is part of my job duties to ensure completeness of the records for this appeal, and all appeals, and to fully participate in the appeals process. At the meeting today, you distributed to everyone a copy of the latest version of your appeal memorandum and this memo served as the focal point of discussion. In addition, several of the Review team members (Mark Melkerson, Neil Ogden, and Kareem Burney) stated that they would specifically review the information cited in your appeal memo (distributed at the meeting) and that they would get back to you with their comments to determine if they agree with your analysis and recommendation to overturn the NSE decision. I am in the process of constructing the minutes for today's meeting and it is essential that I have a copy of your appeal memo in order to construct the minutes.

I respectfully note that you have not included me on relevant correspondence (including an email mentioned at today's appeal meeting) related to this appeal and to other appeals, which I have previously brought to your attention. With regard today's appeal meeting, you mentioned that you had distributed another version of your appeal memo to the Division. However, I have been excluded from that relevant correspondence. I am concerned that without all of this information, including the appeal memo you distributed at today's meeting, I cannot ensure completeness of the appeal records for this file.

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7/8/2009

In your May 29, 2009, ODE-wide email you indicated the following: "The 10.75 appeals process is a part of our regulatory program, and I am committed to managing this program, as with all other premarket programs, with an adherence to good scientific and regulatory principles, and a spirit of transparency to all stakeholders."

In order that I am able to properly perform my job duties, I respectfully request that you provide to me a copy of your appeal memo that was distributed at today's meeting and that you include me on all relevant correspondence for this appeal, and all appeals.

Thank you,

Cindy

Cindy Demian, MSBE
FDA/CDRH/POS
(240) 276- 4023

7/8/2009

**Review of Request for Supervisory Review
Draft: June 25, 2009**

Date:

From: Donna-Bea Tillman, Ph.D, M.P.A
Director, Office of Device Evaluation

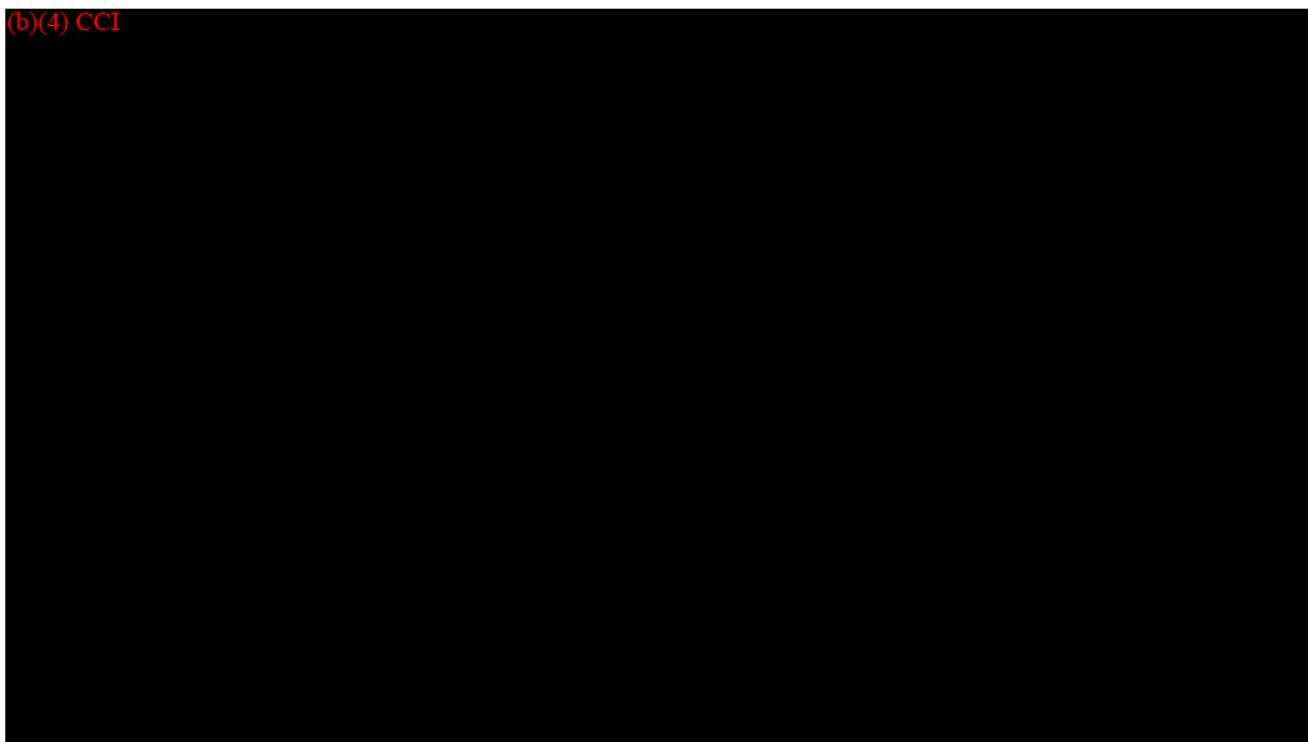
Re: Appeal of K082423, Radiancy No!No! device for the treatment of acne
NSE letter dated December 3, 2008

Action: Reverse NSE and issue SE letter

Background

The Radiancy No!No! (NoNo) is a battery-powered, handheld device indicated for the OTC treatment of individual lesions in mild to moderate inflammatory acne. The device uses a halogen lamp to deliver energy in the 450-2000nm wavelength range to a 50 mm² spot. Treatment time is 10 seconds, and the user is instructed to apply two treatments to each lesion twice a day.

(b)(4) CCI



Review Analysis

Predicate Devices

There are two predicate devices (both with OTC indications) that are the most relevant to this submission: the Tyrell “Zeno”, and the DermaCare “Thermaclear”. I will begin by summarizing the basis for the clearance of each of these devices.

1. Tyrell Zeno (K043377). Reviewer: Richard Felten. There was not a clinical review of this 510k. SE letter issued 6/1/2005.

The Zeno device uses low level heat (119 degF) to treat individual lesions in mild to moderate inflammatory acne. The device is battery powered, and treats a 71 mm² spot size. Treatment is 2.5 minutes per lesion, and the treatment paradigm is two treatments on the first day, and one treatment on the second. This was the first “heat-based” device to treat acne (predicates were low-level light devices).

The study was a double-blinded, randomized controlled trial of 51 subjects with mild to moderate acne. Of note (and as opposed to the NoNo device), subjects with pustular acne were excluded. The investigator selected two comparable blemishes, and one was treated with the Zeno device, the other was treated with a placebo device (Note: The placebo device only achieved a temperature of 94 degF, while the Zeno device reached 119 degF). Photographs of each blemish were taken at each follow-up visit.

Patients maintained a patient diary in which they recorded an assessment of each blemish on each day. The four types of responses were: resolved, improved, no improvement, or worsened. The first day that a blemish was rated as resolved was used to determine the time to resolution. The time to resolution was the pre-specified primary endpoint for the study. Secondary efficacy endpoints included the blinded investigator’s assessment of the treated area. Adverse events were also recorded.

The primary endpoint of the study was met. The median time to resolution for the Zeno device (in hours, and as reported in the patient diary) was 90 (95% CI [69, 118]) as compared to 140 [119, 166], with a $p < 0.0020$ (log-rank test). The percentage of blemishes that resolved or improved, as assessed by the blinded investigator, was also significantly better for the Zeno device (100% for the Zeno device, and 77% for the control at day 5).

It appears from the record that the reviewer primarily relied on the blinded investigator assessment of the percentage of lesions improved or resolved by day 5, and that these results are comparable to those observed for other devices previously cleared for the treatment of facial acne.

2. Dermacare Thermaclear (K060653). Reviewer: Richard Felten. There was not a clinical review of this 510k.

The Thermaclear device uses a nichrome heating element to apply thermal energy to a 127 mm² spot to treat individual pimples in mild to moderate inflammatory acne. Peak temperatures at the skin is 150 degF, and the duration of treatment is 2 sec.

The study included 43 patients with 278 treated lesions. However, because control lesions were not assessed for all of these patients, the review focused on 14 subjects who had 53 lesions treated and 51 control lesions. [Note: In this study, the control lesions did not receive any treatment] Lesions were evaluated by baseline, and on a daily basis out to five days. Assessments were made by a blinded investigator based on a review of photographs. A severity scale of 0-3 was used, with 0 being a non-inflamed lesion, and 3 being a severe visible lesion raised 2mm or more above the skin with erythema extended greater than 1mm. Although not explicitly stated, it appears that the primary endpoint was lesion score at day 5.

At day five, the average lesion score was 0.83 for the treatment group (baseline 1.58) and 1.18 for the control group (baseline 1.62). The reviewer notes that “even non-treated lesions improve over time...however, the treated lesions show a greater degree of improvement”.

A second analysis was performed looking at lesion response, where a severity score of 0 represents “resolved”, and a day 5 score that is lower than baseline represents “improvement”.

	Treated group	Control group
Resolved	38%	17%
Improved	26%	29%
Resolved/Improved	64%	46%

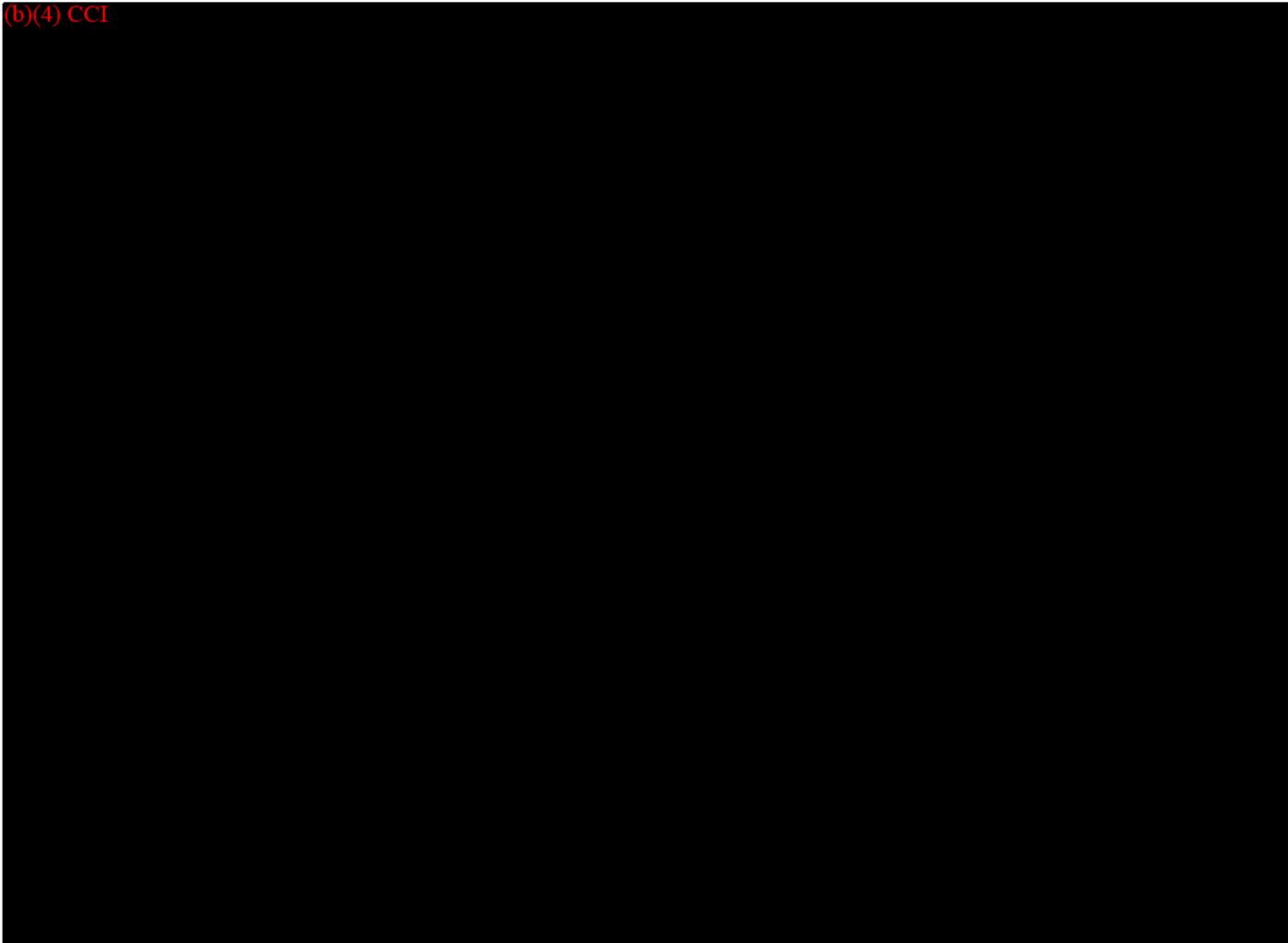
The reviewer notes that “Again this indicates that treatment does provide benefit with a greater number of lesions in the treated group having a score of 0 [resolved] by day 5”. The reviewer goes on to note that: “In terms of comparison to the predicate device, the Zeno device, both of these devices essentially reduce the time to clearance of acne lesions. The endpoint for the Zeno study was time to clearance with the treated lesion demonstrating a quicker time to clearance”.

Note: Although not explicitly mentioned by the reviewer, the data table provided by the firm (IMAGE p.21) shows that even in the treated arm, some subjects have a severity score at day 5 that is greater than the score at baseline (e.g., patient 140 has a lesion that is rated “1” at baseline at “2” at day 5, and patient 144 has a lesion that is “2” at baseline and “3” at day 5). In other words, some of the treated patient get worse. This will be important in considering the NoNo results.

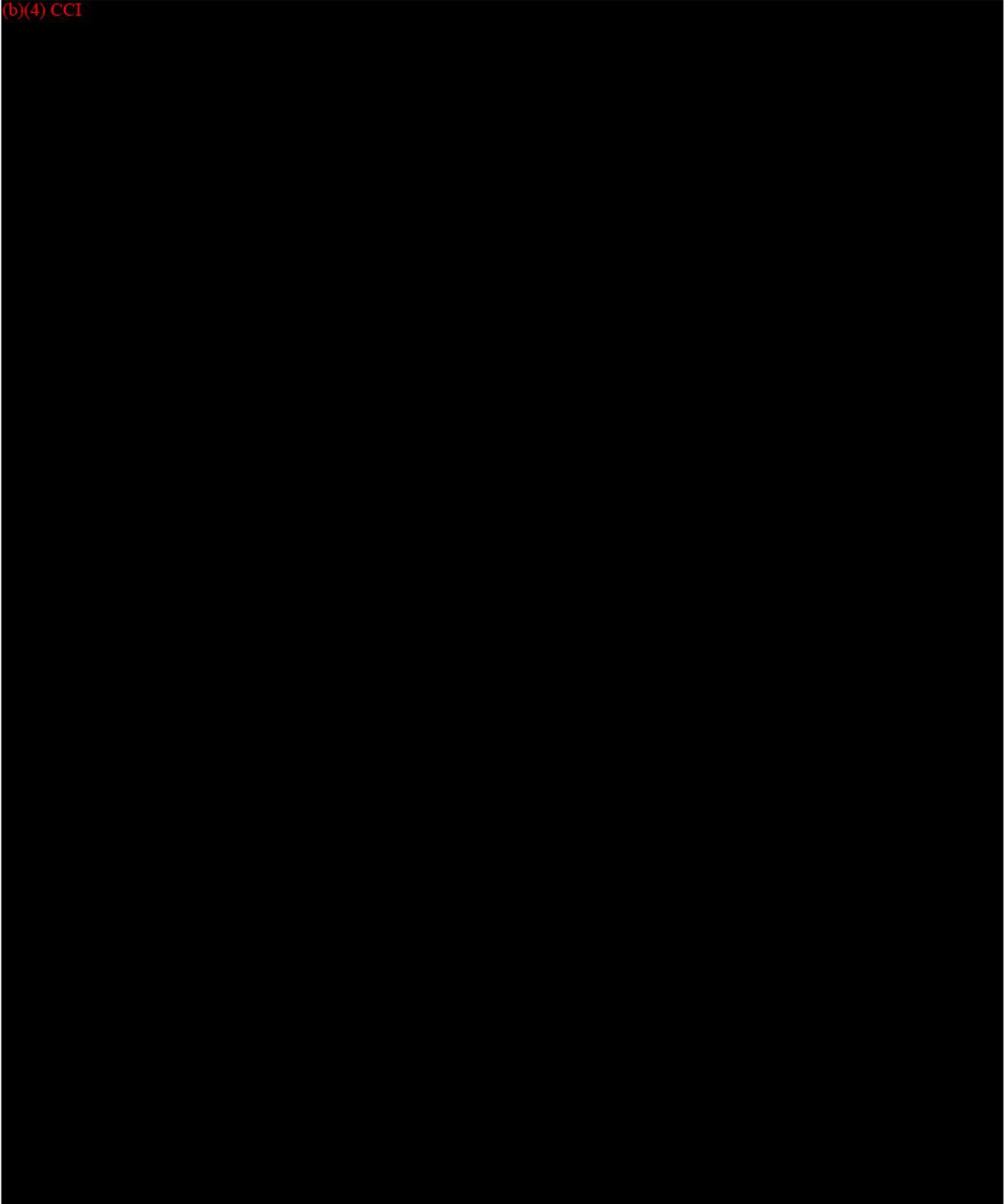
TREATED							UNTREATED					
	Baseline	Day 1				Day 5						
140	1	1	1	1	1	1	D	1	1	1	1	0
	2	1	2	3	3	2	E	1	1	1	1	1
	3	1	1	1	1	1	A	1	1	1	1	1
142	1	2	3	2	1	1	A	2	2	2	2	2
	2	1	1	0	0	0	B	1	2	2	2	2
	3	2	2	2	1	1	C	2	1	1	1	1
	4	3	3	2	1	1	D	2	1	1	1	1
	5	1	1	2	1	1	E	1	1	1	1	1
144	1	2	1	1	1	1	F	1	1	1	1	1
	2	3	2	3	2	2	B	1	3	2	2	2
	3	1	1	0	0	0	D	1	1	1	1	1
	4	2	2	2	2	3	E	1	1	2	2	1
	5	2	3	2	1	1	F	1	2	1	1	1
	6	1	2	2	1	0						
	7	3	3	3	3	2						

NoNo Study

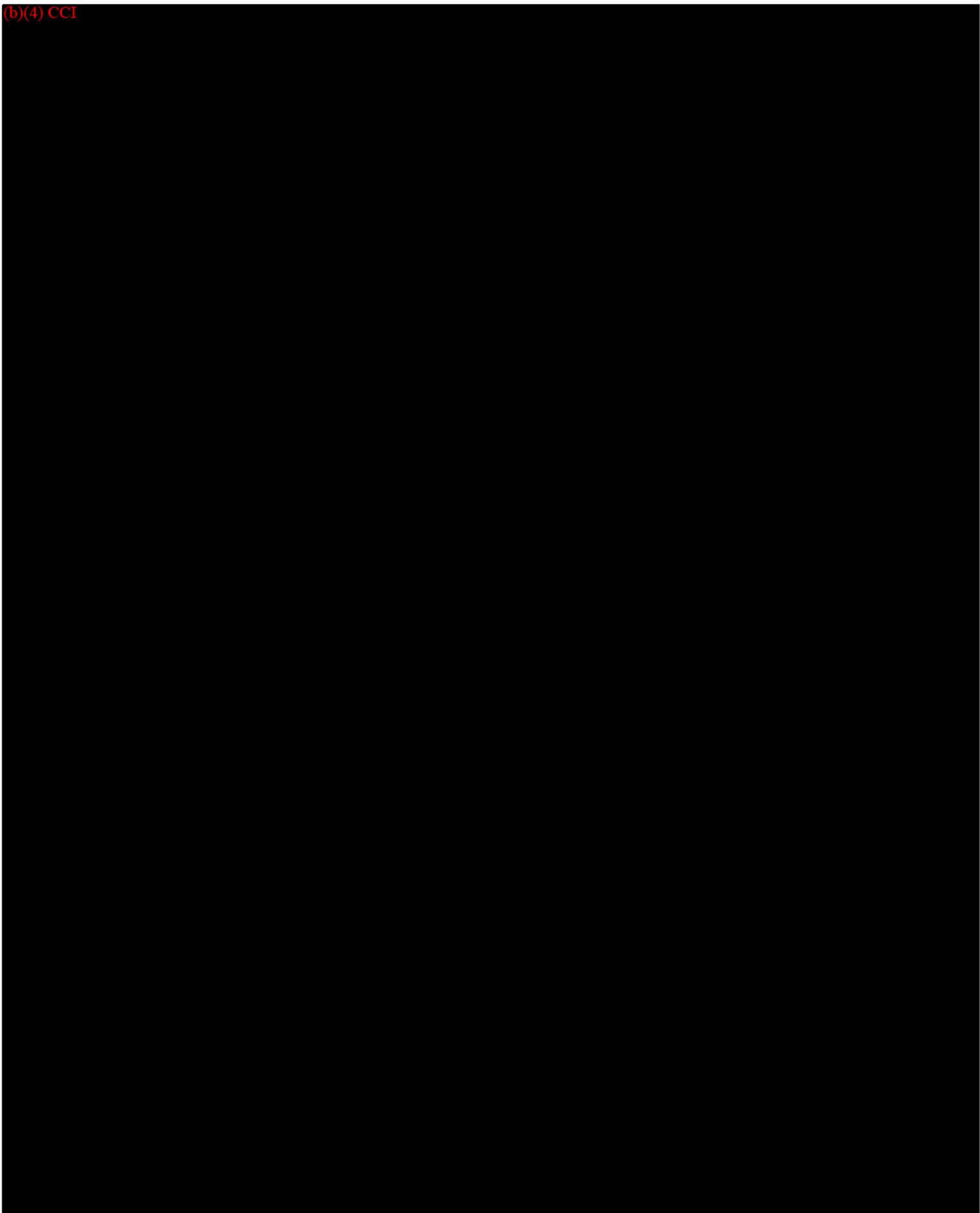
(b)(4) CCI



(b)(4) CCI

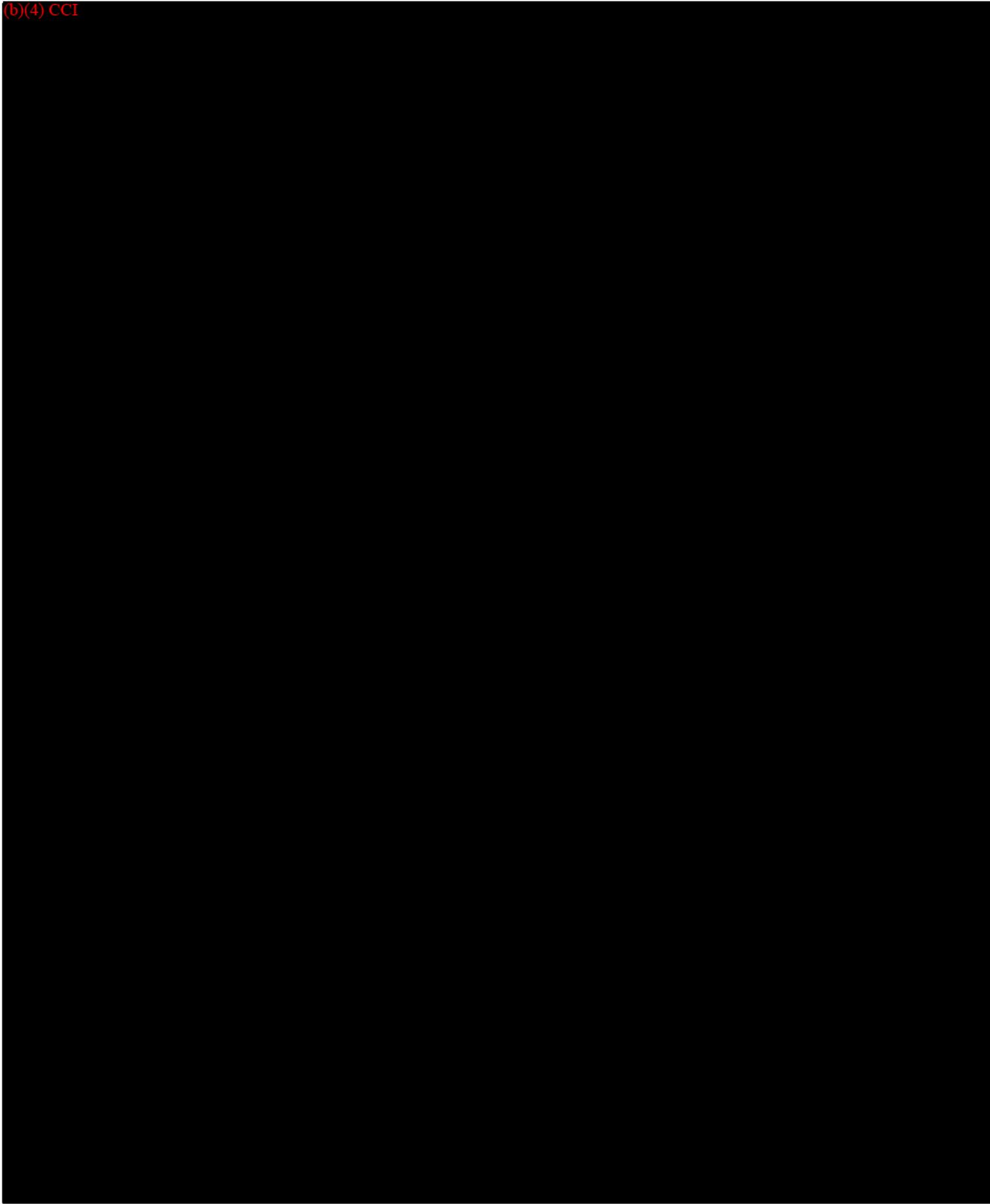


(b)(4) CCI



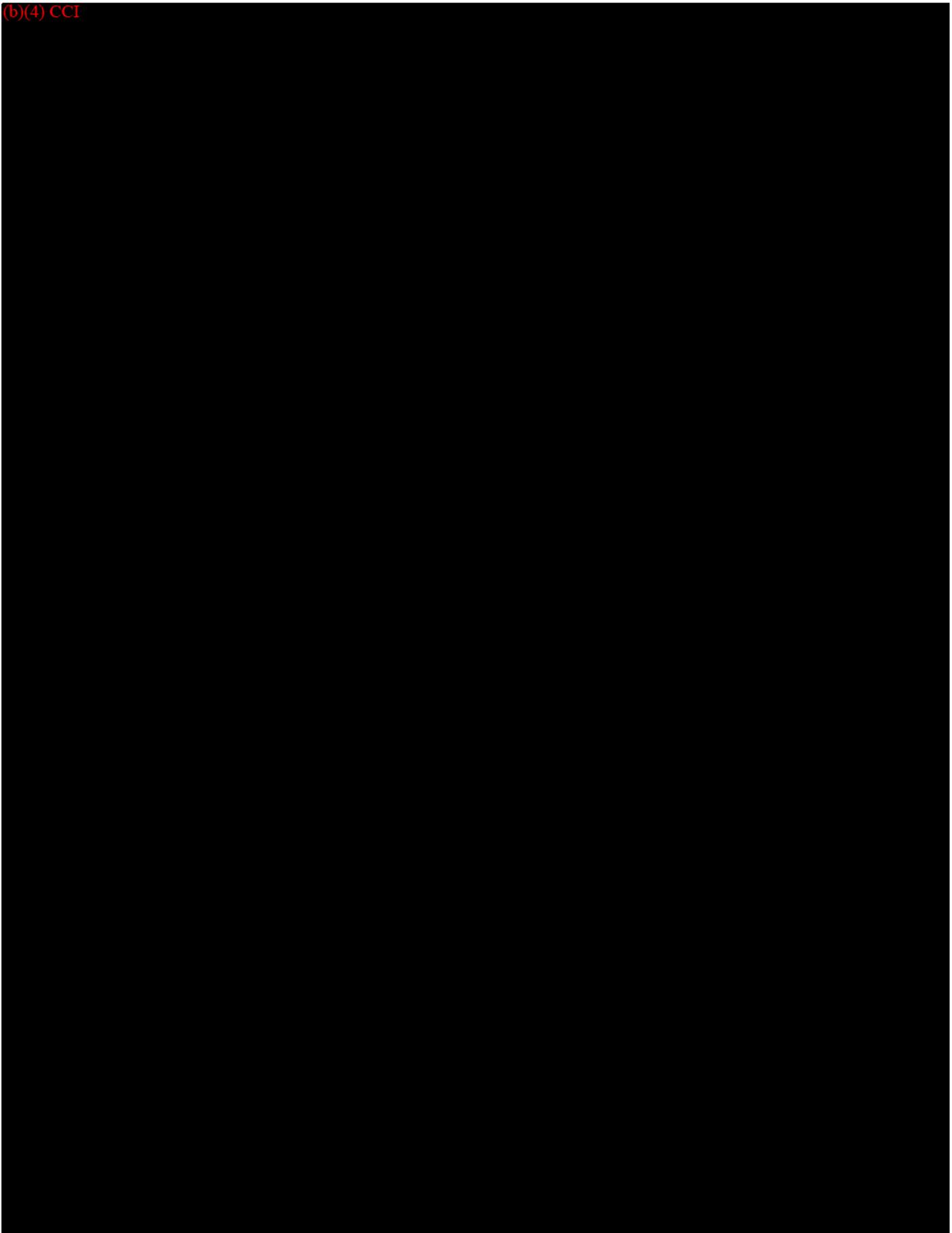
61

(b)(4) CCI

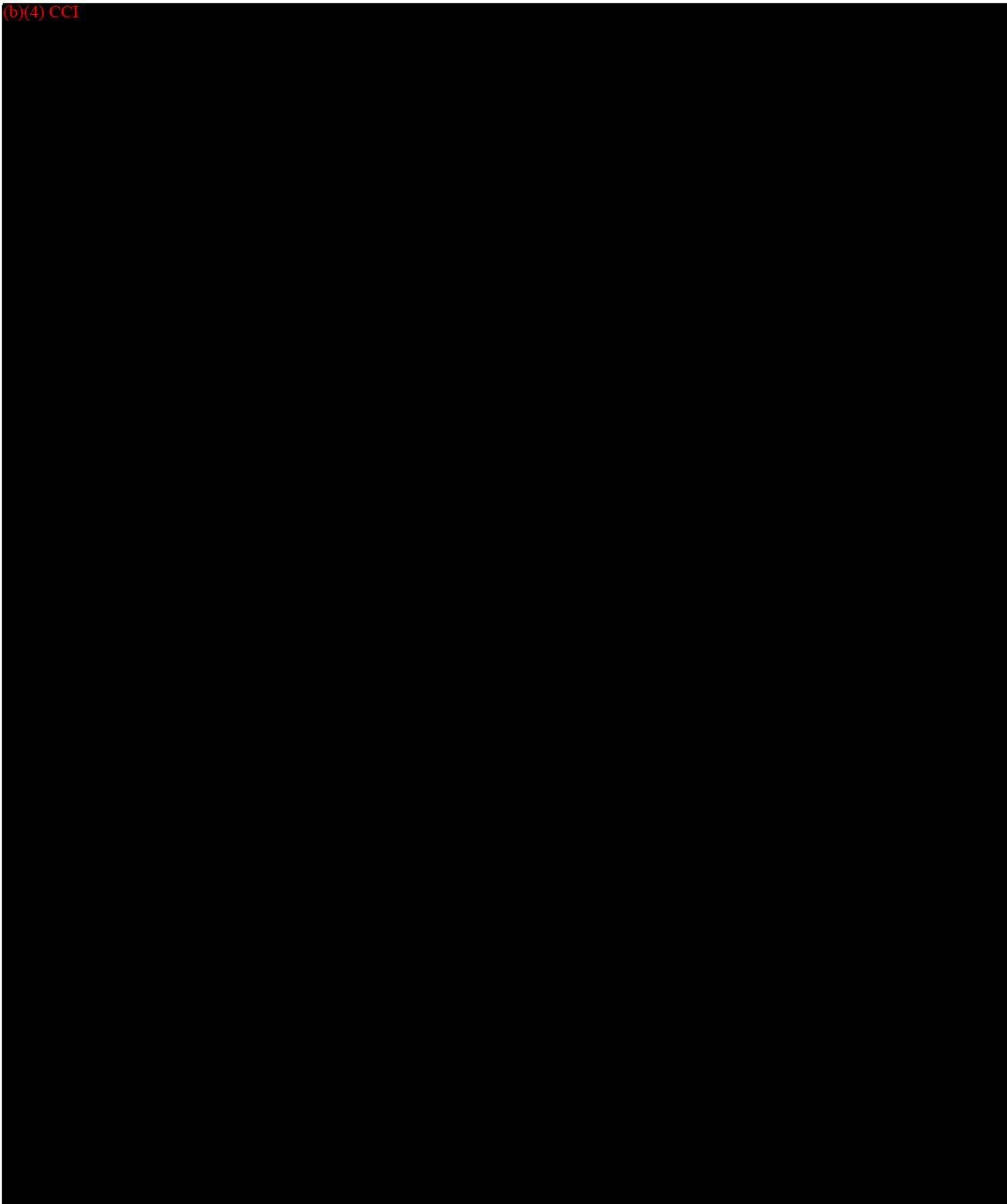


62

(b)(4) CCI



(b)(4) CCI



compare patient-outcomes across studies due to potential differences in patient characteristics and the time course of the natural progression of acne.

Decision

After carefully reviewing all the facts in this submission and in the predicate device submissions, meeting with the sponsor, meeting multiple times with the review team, and consulting with Dr. Luke, I believe that the results of the NoNo clinical study are sufficient to demonstrate that the device has equivalent effectiveness for the purposes of demonstrating substantial equivalence.

I met with the division on June 25, 2009, to share my draft memo and present my conclusions. In attendance were Mark Melkerson (division director), Neil Ogden (branch chief), Kareem Burney (reviewer), Markham Luke (ODE clinical deputy) and Cindy Demian (POS). The reviewer noted that the primary basis for his NSE recommendation was the fact that the percentage of patients who had resolution with the NoNo device was much lower than with the predicate Zeno device. When I asked about the Thermaclear device, I was informed that it was not used for comparison, because the technology of the NoNo device was more similar to the Zeno device. I would note that all three devices have the identical indications.

I noted that it is appropriate to try to directly compare clinical study results, for the following reasons:

1. We don't know if the populations were comparable, and there are many known and unknown covariates that can impact on the progression of acne. I have already noted one example: The Zeno study excluded patients with pustular acne, while these patients were included in the NoNo study.
2. The results for the control patients in the various studies were clearly different, further suggesting that there were differences in the patient populations.

Percent Resolved/Almost resolved at Day 5

	Treated	Control
Zeno	100%	77%
NoNo	70%	56%
Thermaclear	38%	17%

3. The scoring methodologies were different in the two studies. The Zeno study used a 4-point scale (resolved, improved, no difference, worse) while the NoNo study used a 5-point scale, that also included "almost resolved". The Thermaclear study also used a 4-point scale.

Following the meeting, I emailed a draft of my review memo to the review team and division and asked for written comments by COB July 2.

Demian, Cindy

From: Demian, Cindy
Sent: Tuesday, February 17, 2009 5:56 PM
To: Tillman, Donna-Bea
Cc: Rosecrans, Heather S.
Subject: No! No! Skin Meeting Minutes
Attachments: K082423-Meeting Minutes for NSE Appeal- actual record of what was said in meeting.doc

Donna-Bea,

Attached are my meeting minutes- which is the actual record of what was said during the appeal meeting. Since there was a lot of fast talking and people talking over one another, I may have missed a few comments. However, I would like to send this out to you and others who attended to capture what was said before we all forget. Please indicate how you would like to proceed and let me know if you have additional comments/suggestions.

Thanks,

Cindy

4/1/2009



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service Food and Drug Administration

Meeting Minutes

DATE February 17, 2009

FROM Cindy Demian, M.S.
Biomedical Engineer

TO k082423

RE Radiancy, Inc.
No! No! Skin

Kareem Burney, Lead Reviewer of **k082423**
Appeal of ***NSE Decision*** dated 12/3/08

DIVISION DGRND/GSDB

CONTACT Zvi Ladin, Ph.D., Boston MedTech Advisors
(781) 407-0900 x 104
(781) 407-0901(fax)
Email: zladin@bmtadvisors.com

Meeting Attendees:

FDA-

Donna- Bea Tillman, Ph.D., Office Director (DBT)
Markham Luke, MD, Clinical Deputy Director
Heather Rosecrans, 510(k) Staff
Cindy Demian, MSBE, 510(k) Staff
Mark Melkerson, MS, DGRND Director (MXM)
Neil Ogden, MS, GSDB Branch Chief
Kareem Burney, Lead Reviewer

Firm-

Dolev Rafaeli, Ph.D., CEO of Radiancy
Neil Sadick, MD, Clinician, Study PI, Sadick Dermatology
Zvi Ladin, Ph.D., Principal, Boston MedTech Advisors

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Via Phone-

(b)(4)

(b)(4)

Firm provided and went over slide presentation.

DBT- (b)(4), What is your relation with the firm?

(b)(4) - I am a clinical researcher for the firm. The company has paid for the research.

DBT- Do you own any stock in the company? No.

DBT- So, let's say I am a patient with acne. Does the patient get to choose the treatment? Could you explain as it is not clear?

Dr. Ladin- Yes, The patients are randomized across the study. Four lesions per patient.

Dr. Luke- It emits light and no heat is given, is that correct? The firm indicated yes.

DBT- There is no reason for the patient to receive heat.

(b)(4) - I am a professor at Cornell University for the past 25 years conducting research. We have been involved in conducting this kind of research in the office as well as home treatment. Patients are extremely satisfied. There are no safety concerns.

DBT- What kinds of patients do you see?

(b)(4) - Patients with inflammatory acne. Not patients that are no treatment periods. Most patients use OTC products. Patients are able to use our product in the office to treat themselves and at home.

DBT- Tried to treat themselves? There are patients that have pre-menstrual cysts without going to the physician. If I am a patient, in the real world setting, how do you know that patients are going to use this device in the same manner as in the physician's office?

(b)(4) - Yes, as soon as these technologies are becoming more available, patients are able to treat themselves in the same manner as being in the physician's office.

Dr. Luke- Is it a timed turn off? Yes.

(b)(4) - Patients have mild, moderate, and severe acne. There was no limit [during the study] as to the number of times the patient could use the device.

Cosmo-Dermatology Article.

Dr. Luke- As compared to the placebo, is there a papules to pustula? Is there a mismatch? To actually what was seen on the patient? The firm performed biostats that did not match as the evidence was not convincing.

Dr. Luke- The Zeno Study- how were patients graded?

(b)(4) - It [Acne] had to be gone to be considered gone.

Dr. Luke- Acne is not going to stay on the face forever. Was a half life study conducted?

(b)(4) - No, with heat & light you can treat acne. We considered this device as a part of a maintenance program. You can treat inflammatory acne. This is the majority of patients that have this. There are single as well as multiple lesions in which one can treat.

Other questions from the firm? No.

Dr. Luke- You indicated that there is time rather temperature. Have you done any studies that may take in to consideration the room temperature and the effect, especially if the room is colder?

Firm- No, as there ambient air is nominal.

DBT- How deep is the light?

Firm- We are confused about the decision and would appreciate you reconsidering the NSE decision.

MXM- When you look at predicates, the information is not consistent with the data that we saw and what was reviewed.

DBT- We have other ways to deal with this issue that we can refer to the Office of Compliance. However, in terms of next steps, we have the following options:

- 1) Reconsider the decision
- 2) Go another round, and have the division review the labeling, other sections that where not initially reviewed during the review, etc.

APPEAL MEETING LOG

DATE February 17, 2009

DOCUMENT NUMBER k082423

FIRM No! No! Skin Appeal

FIRM ATTENDEES

NAME & TITLE

Dolev Rafaili

(b) (6)

Zvi Ladin

(b) (6)

CEO & President

(b)(4)

FDA ATTENDEES

NAME & TITLE

MARK N MELKERSON

Markham Love, MD

Neil Ogden

Kareem S. Bracey

Donna Bea Tillman

Cindy Demuau

Heather Rosecrans

DIRECTOR, DGRND

Deputy Office Director ODE

Chief GSDB

Reviewer GSDB

Director, ODE

510(K) Director

AGENDA SUBMITTED

YES NO

SLIDES

YES NO

K082423 - No!No!Skin

Demian, Cindy

From: Zvi Ladin [zladin@bmtadvisors.com]
Sent: Monday, January 26, 2009 3:40 PM
To: Gornick, Mary Ann
Subject: Radiancy Meeting on February 17, 2009
Importance: High
Sensitivity: Confidential
Attachments: 2009_02_17_FDA no!no! Skin Meeting.pdf; 2009_02_17_FDA no!no!Skin Presentation_Final.pdf

Dear Ms. Gornick:

Enclosed please find the information package that was shipped today by overnight Express Mail to FDA's Document Mail Center. It includes a cover letter, the Power Point presentation and a copy of a paper documenting the clinical performance of the Zeno device (one of the predicate devices for the submission). Due to its size (~6MB) it was not sent electronically, so the files included with this mail message are:

1. Cover letter
2. Power Point presentation

The following tables list the participants at the meeting that will travel to Rockville, Maryland, and the two participants that will listen-in from Israel.

Meeting participants:

Name	Title	Organization	US Resident
Dolev Rafaeli, PhD	CEO	Radiancy	No
Neil Sadick, MD	Clinician, Study PI	Sadick Dermatology	Yes
Zvi Ladin, PhD	Principal	Boston MedTech Advisors	Yes

Phone participants:

Name	Title	Organization
(b)(4)		

Please do not hesitate to contact me if I can provide any additional information.

Sincerely,

Zvi Ladin

Zvi Ladin, Ph.D.
 Boston MedTech Advisors
 990 Washington Street Suite 204
 Dedham, MA 02026-6717

Phone: (781) 407-0900/x104
 Fax: (781) 407-0901
 Cell: (617) 921-4600
 e-mail: zladin@bmtadvisors.com

2/17/2009

Web: www.bmtadvisors.com

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2/17/2009

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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January 26, 2009

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Attn.: Mr. Mark Melkerson, Director, Division of General, Restorative and Neurological
Devices, Office of Device Evaluation, Center for Devices and Radiological Health

Re: 510(k) Premarket Notification for the no!no! Skin™ Device #K082423

Dear Mr. Melkerson:

Enclosed please find three copies of the presentation we intend to make during the meeting, scheduled for February 17, 2009 at 4:00 pm at the FDA office on 9200 Corporate Boulevard, Rockville, Maryland. The presentation covers the following topics:

1. Overview of the main technological features and the regulatory history of the predicate devices.
2. Highlights of the clinical protocol:
 - a. Comparison to the clinical protocols of predicate devices.
 - b. Principal investigators' information.
3. Lesion resolution data compared to predicate devices (provided in original submission and repeated in the October 23, 2008 correspondence).
4. Summary of interactions with FDA during the review process:
 - a. September 24, 2008 request for additional information with sponsor response on October 2, 2008.
 - b. October 21, 2008 request for additional information with sponsor response on October 23, 2008.
 - c. December 3, 2008 NSE letter with sponsor response on December 18, 2008.
5. Highlights of Zeno's performance based on a published paper by Gold et. al. 2007, describing an 80% treatment time protocol (attached to this correspondence)

990 Washington Street, Suite 204, Dedham, MA 02026 ► Phone: 781.407.0900 ► Fax: 781.407.0901
www.bmtadvisors.com

6. Appendix extracted from original submission and correspondence dated October 2, 2008) detailing:
 - a. Highlights of a technical comparison of candidate and predicate devices.
 - b. Highlights of skin and eye safety

Please refer any communications regarding this information to: Zvi Ladin, Ph.D., Boston MedTech Advisors, Inc. 990 Washington Street, Suite 204, Dedham, MA 02026, Ph: (781) 407-0900 / x104, FAX: (781) 407-0901, Cell: (617) 921-6400, E-mail: zladin@bmtadvisors.com.

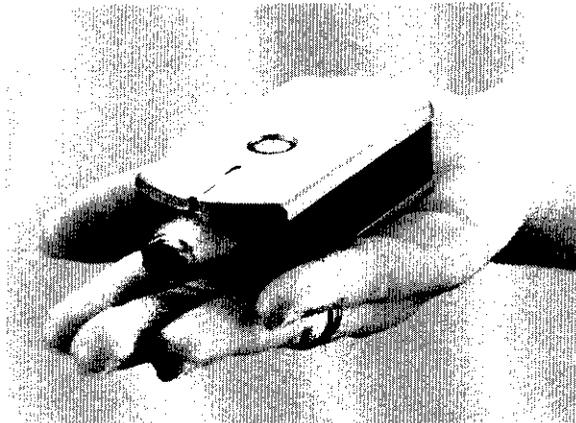
Sincerely yours,

Zvi Ladin, PhD, Principal, Boston MedTech Advisors, Inc., for
Dolev Rafaeli, CEO, Radiancy, Inc.

Encl:

1. Power Point presentation slides.
2. Gold, MH, Sadick, NS, Bradshaw, VL and Boring, MM. A randomized, controlled, double-blind study of localized low-heat treatment of acne lesions. *Cosmetic Dermatology* 20[8]:495-499, 2007.

Radiancy no!no!Skin™ OTC Acne Device (K082423)



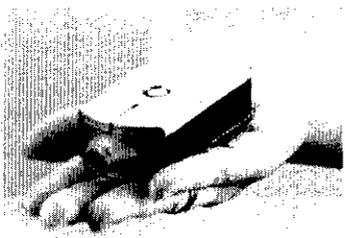
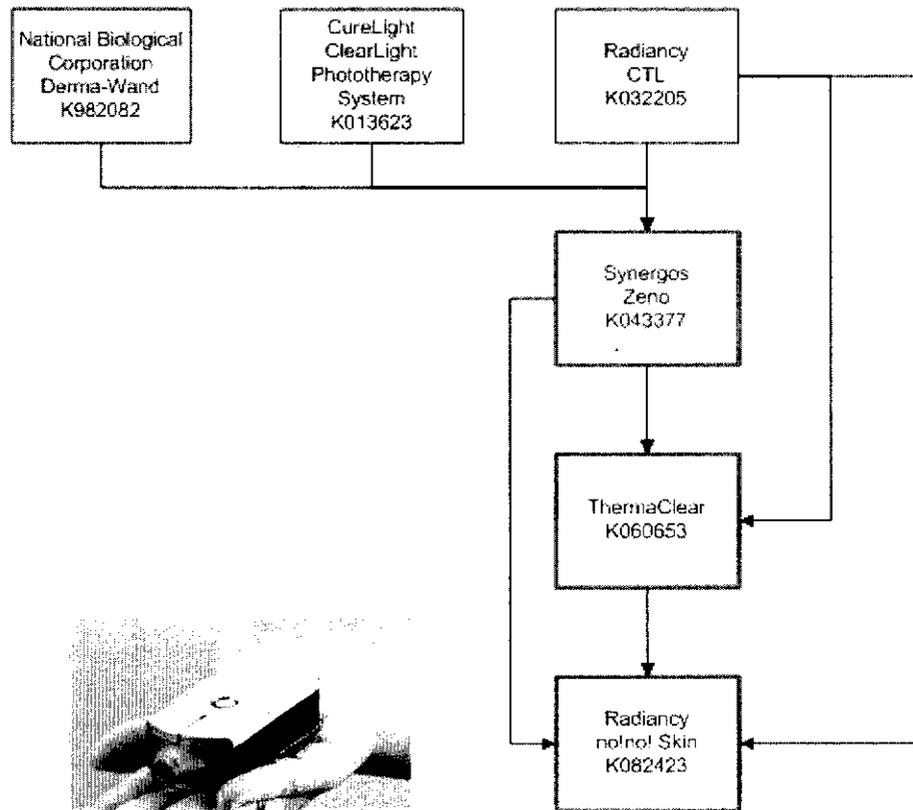
Summary of Clinical Study Results and Comparison to Predicate Devices

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Regulatory History of OTC Acne Treatment Devices

Predicate History



Technical Highlights – no!no! Skin

- Halogen Lamp
- Light and Heat energy
 - Same as Radiance's CTL (K032205)
- Battery powered
- Skin and eye safe
 - Appendix attached

Summary of FDA Correspondence - II

10/21/2008 – FDA Request for Additional Information	10/23/2008 – Sponsor Response
<ul style="list-style-type: none"> • Lesion improvement is not an endpoint used to support requested indication 	<ul style="list-style-type: none"> • Lesion resolution analysis provided using PLRS
<ul style="list-style-type: none"> • Time to resolution required as study endpoint 	<ul style="list-style-type: none"> • Time to resolution based on the Kaplan Meier curves provided
<ul style="list-style-type: none"> • Statistically significant difference between active and placebo devices has to be shown 	<ul style="list-style-type: none"> • Statistically significant difference between lesions treated by active and placebo devices documented: <ul style="list-style-type: none"> ▪ Percentage of lesions cleared ▪ Clearance rate ▪ Time to resolution
<ul style="list-style-type: none"> • OTC labeling issues identified and will be disclosed following resolution of device's effectiveness 	

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Summary of FDA Correspondence - III

12/3/2008 – NSE Letter	12/18/2008 – Sponsor Response
<ul style="list-style-type: none"> • Performance data submitted did not demonstrate same safety and effectiveness as legally marketed devices 	<ul style="list-style-type: none"> • Efficacy comparison to predicate devices showed similar rate of complete clearance • No safety issues
<ul style="list-style-type: none"> • Device classified as class III 	
<ul style="list-style-type: none"> • PLRS based analysis of time to resolution needed 	<ul style="list-style-type: none"> • PLRS based analysis of time to resolution provided in 10/23/2008 response
<ul style="list-style-type: none"> • Deficiencies in past responses to requests for additional information <ul style="list-style-type: none"> ▪ 9/25/2008 – Time to Improvement data ▪ 10/11/2008 – Direct comparison of time to resolution to predicate devices 	<ul style="list-style-type: none"> • Past responses: <ul style="list-style-type: none"> ▪ 9/25/2008 – Analysis of improvements in lesions and patients provided <u>per specific FDA's request</u> ▪ 10/21/2008 correspondence assumed (no correspondence dated 10/11/ 2008) ▪ Lesion resolution information provided per specific FDA's request ▪ <u>No specific request issued for direct comparison to predicate devices</u>

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Basis for FDA's NSE Decision

- “The reason for this failure is that by day 5 the OTC predicate devices were able to show complete resolution (the lesions were either fully resolved or almost resolved) of the lesions using the active device in their clinical study, while your device does not show complete resolution of the lesions.”

h8

Comparison to Placebo and to Predicates

	No!No! Skin	Zeno (white paper)	ThermaClear (web summary)
Percentage of Lesions Fully Resolved by day 5	50%	55%	44%
Kaplan Meier Mean Time to Resolution [days]	3.3	4	NA
Percentage of Lesions Fully Resolved and almost resolved by day 5	67%	NA	NA

- Similar fraction of lesions completely resolved – compared to both predicates
- Faster time to resolution than Zeno
- Statistically significant difference between active and placebo arms.

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Zeno Based on Gold & Sadick, 2007

Trial highlights	Zeno
Blinding	Double
Placebo	Yes
Treatments	3X120s (80% of original duration)
Lesions Improved or Resolved Sooner with Device % (# / total)	50% (7 / 14)
Lesion Improved or Resolved Sooner with Placebo	29% (4 / 14)
No Difference Between Device and Placebo	21% (3 / 14)

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Summary of Radiancy's Position

- The no!no!Skin clinical study
 - Followed FDA approved protocol including multiple quantitative efficacy measures
 - Statistically significant differences between active and placebo arms
- no!no! Skin effectiveness is substantially equivalent to results obtained with the Zeno and Thermaclear devices
- Radiancy therefore respectfully requests the FDA to reconsider the NSE decision

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RADIANCY™

Appendix

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RADIANCY™

Technical Comparison to Predicate Devices

Feature	<i>no!no! Skin</i> ™	Zeno™	ThermaClear™
FDA Clearance	K082423 OTC	K043377 OTC	K060653 OTC
Intended Use	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne
Energy Source	Light & Heat (LHE) Halogen lamp	Low level heat, 49.4°C Heating element	Nichrome heat element
Wavelengths	450-2000 nm	NA	NA
Energy delivery duration	10 sec	2.5 min	2 sec
Spot size	8 mm dia. 50 mm ²	0.25 in (71 mm ²)	0.5 in (127 mm ²)
Max fluence	6 J/cm ²	NA	NA
Electical input	Rechargeable batteries	Rechargeable batteries	2 AA Batteries
Dimensions	145 X 36 X 26 mm	114 X 38 X 13 mm	124 X 53 X 28 mm

b8

Skin and Eye Safety

		no/nol Skin	Comments
Power Source		Rechargeable Batteries	Same as Zeno 2 AA for ThermoClear
Maximim Fluence		6 J/cm ²	Same as ClearTouch Lite™ (K060411)
Maximim Skin Temperature		40.4°C	49.4°C – Zeno Element
Eye Safety: Max Values / Exposure Limit	Photoretinitis of Retina [W/cm ²]	0.6 / 250	Actual power density delivered / Exposure limit values Based on DIRECTIVE 2006/25/EC – detailed analysis provided in October 2, 2008 correspondence
	Retinal Burn [W/cm ²]	0.6 / 707	
	Corneal Burn – Cataractogenesis of Cornea Lens [W/cm ²]	0.6 / 6.4	



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 03 2008

Radiancy (Israel) LTD.
% Boston MedTech Advisors, Inc.
Zvi Ladin, PhD
990 Washington Street, Suite 204
Dedham, Massachusetts 02026

Re: K082423
Trade Name: no!no! Skin™
Regulatory Class: III
Product Code: GEX
Dated: October 23, 2008
Received: October 24, 2008

Dear Dr. Ladin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We have determined the device is not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to any device which has been reclassified into class I (General Controls) or class II (Special Controls), or to another device found to be substantially equivalent through the 510(k) process. This decision is based on the fact that the performance data you have provided on September 25, 2008 and October 11, 2008 did not demonstrate your device to be as safe and effective as legally marketed devices.

You may resubmit a new 510(k) if you have data you believe can show your device to be substantially equivalent.

Therefore, this device is classified by statute into class III (Premarket Approval), under Section 513(f) of the Federal Food, Drug, and Cosmetic Act (Act).

Section 515(a)(2) of the Act requires a class III device to have an approved premarket approval application (PMA) before it can be legally marketed, unless the device is reclassified.

Any commercial distribution of this device prior to approval of a PMA, or the effective date of any order by the Food and Drug Administration re-classifying this device into class I or II, would be a violation of the Act. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

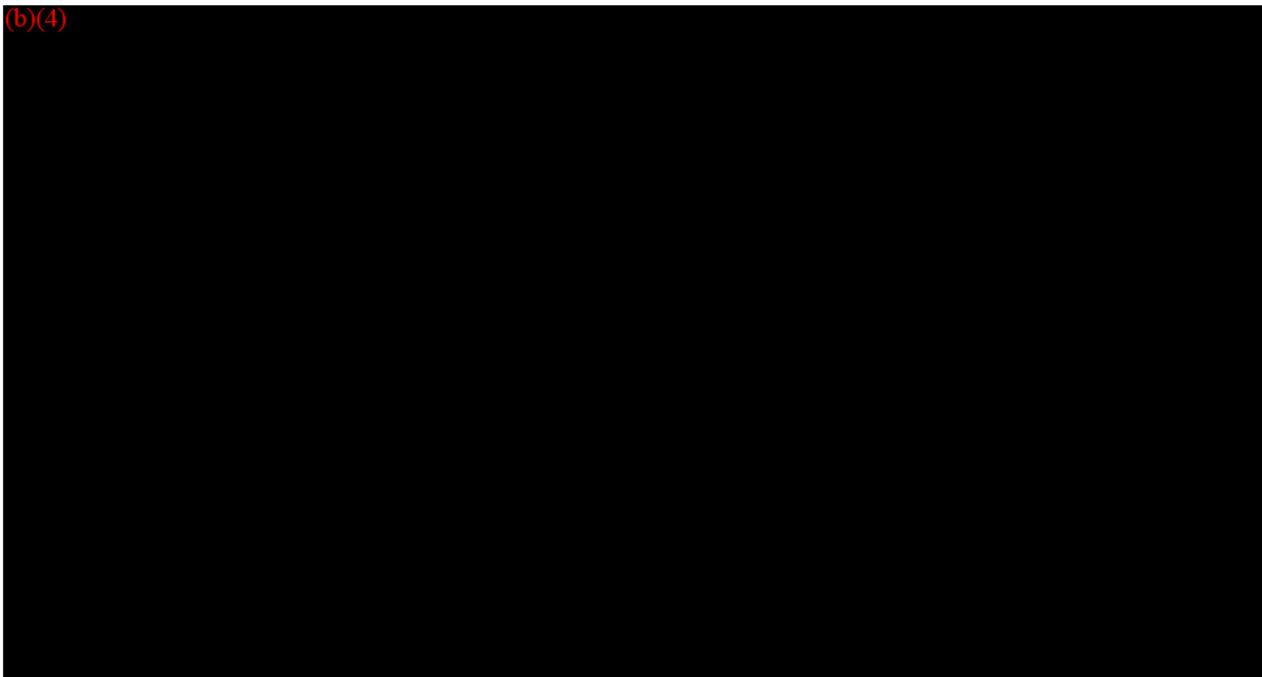
If you wish to pursue the marketing of this device and need information or assistance for preparing investigational or premarket submissions, please contact the Division of Small

Page 2 – Zvi Ladin, PhD

Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address www.fda.gov/cdrh/industry/support/index.html.

If you decide to submit a new 510(k) you should submit a complete submission which includes the information identified in Title 21, Code of Federal Regulations (21 CFR), Section 807.87 and follows the formatting specified in 21 CFR, Section 807.90, and also refer to our document, titled Guidance for Industry and FDA Staff - Format for Traditional and Abbreviated 510(k)s which is available from the Internet at: www.fda.gov/cdrh/ode/guidance/1567.pdf. In addition, please ensure that any new 510(k) includes information that addresses the following issues:

(b)(4)



The information requested above represents the issues that we believe need to be resolved before our review of a new 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies should you decide to submit a new 510(k). We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the document, "A Suggested Approach to Resolving Least Burdensome Issues". It is available on the Internet at www.fda.gov/cdrh/modact/leastburdensome.html.

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Page 3 – Zvi Ladin, PhD

If you have any questions concerning the additional information that should be submitted in a new 510(k) submission, please contact Mr. Kareem Burney at (240) 276-3600.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



December 18, 2008

FDA CDRH DMC

DEC 19 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Received

K-21

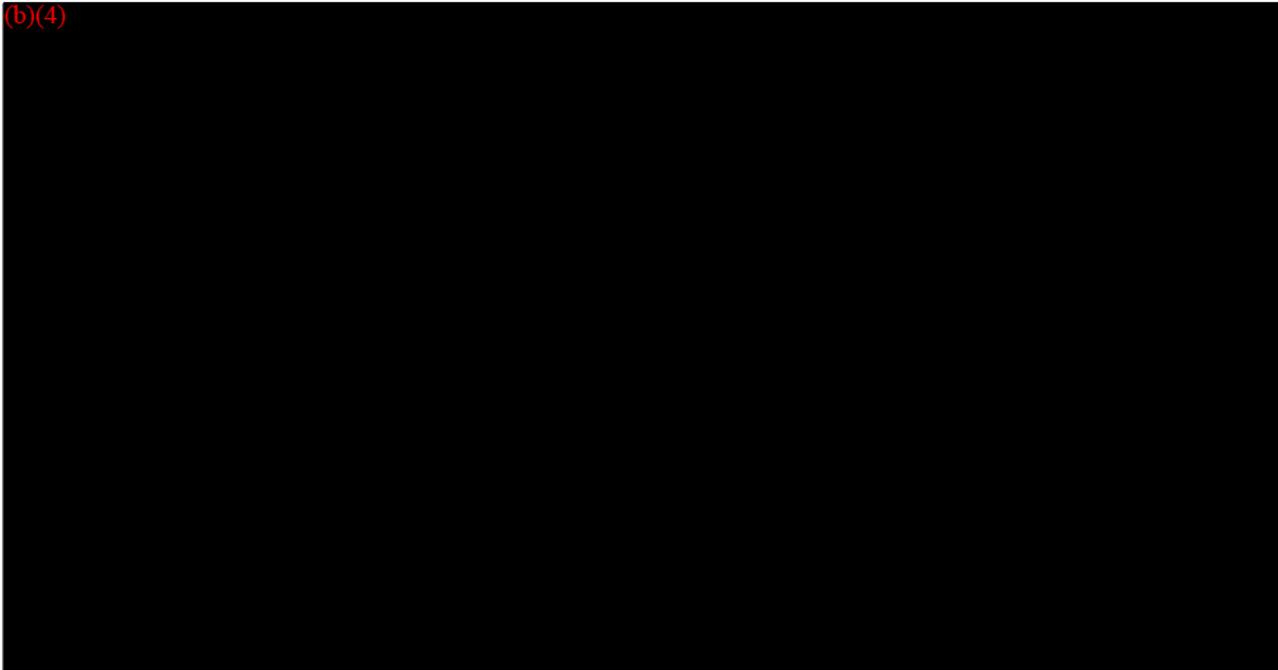
Attn.: Mr. Mark Melkerson, Director, Division of General, Restorative and Neurological Devices, Office of Device Evaluation, Center for Devices and Radiological Health

Re: 510(k) Premarket Notification for the no!no! Skin™ Device #K082423

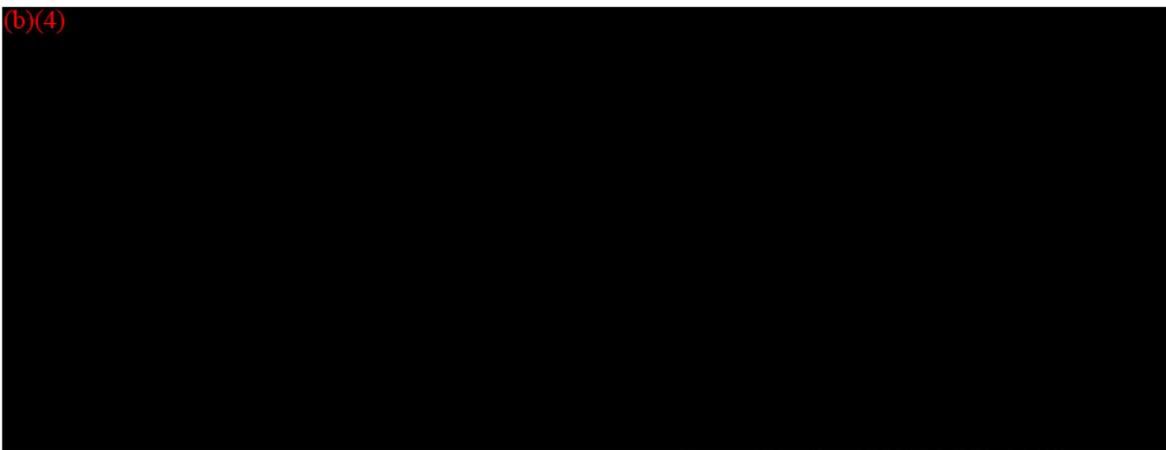
Dear Mr. Melkerson:

This letter is intended to elucidate information included in 510(k) pre-market notification #K082423, no!no! Skin™ Device. The sponsor of the submission, Radiancy (Israel), Ltd believes that due consideration of this information strongly supports the substantial equivalence claim of the device, and therefore respectfully requests the FDA to reconsider its Not Substantially Equivalent ('NSE') decision issued on December 3, 2008. The sponsor further requests to hold a meeting to discuss the clinical equivalence between the candidate and predicate devices, and to suspend the 30-day time limit for appealing FDA's decision, until this clarification process has run its course.

(b)(4)

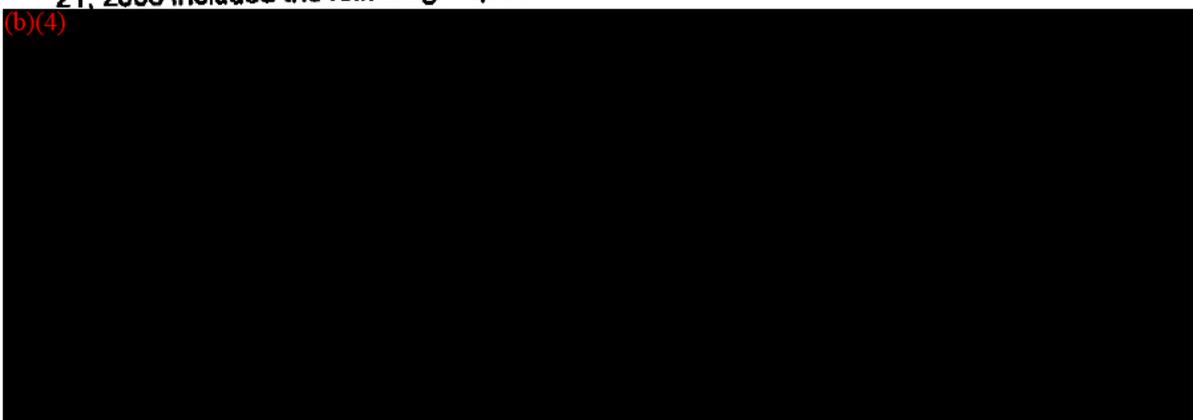


(b)(4)



3. *Data requested on October 21, 2008* – The letter issued by the FDA on October 21, 2008 included the following request:

(b)(4)

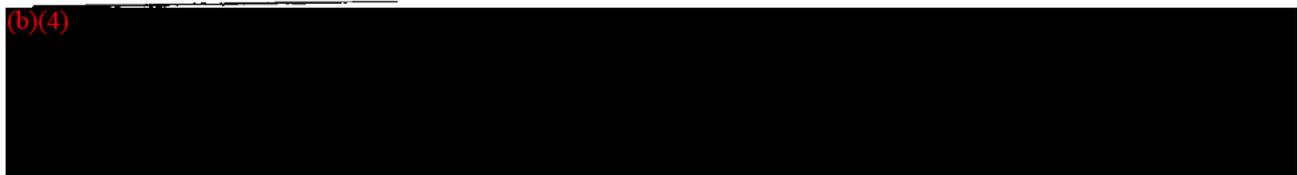


Since time to lesion resolution was included as an endpoint in the original study (Section 20-D, Pg. 14 of 49), the response (submitted on October 23, 2008) centered on the reanalysis of the data for the fully resolved lesions based on the PLRS, showing the statistically significant difference between the actively-treated and placebo-treated lesions (last sentence in above paragraph).

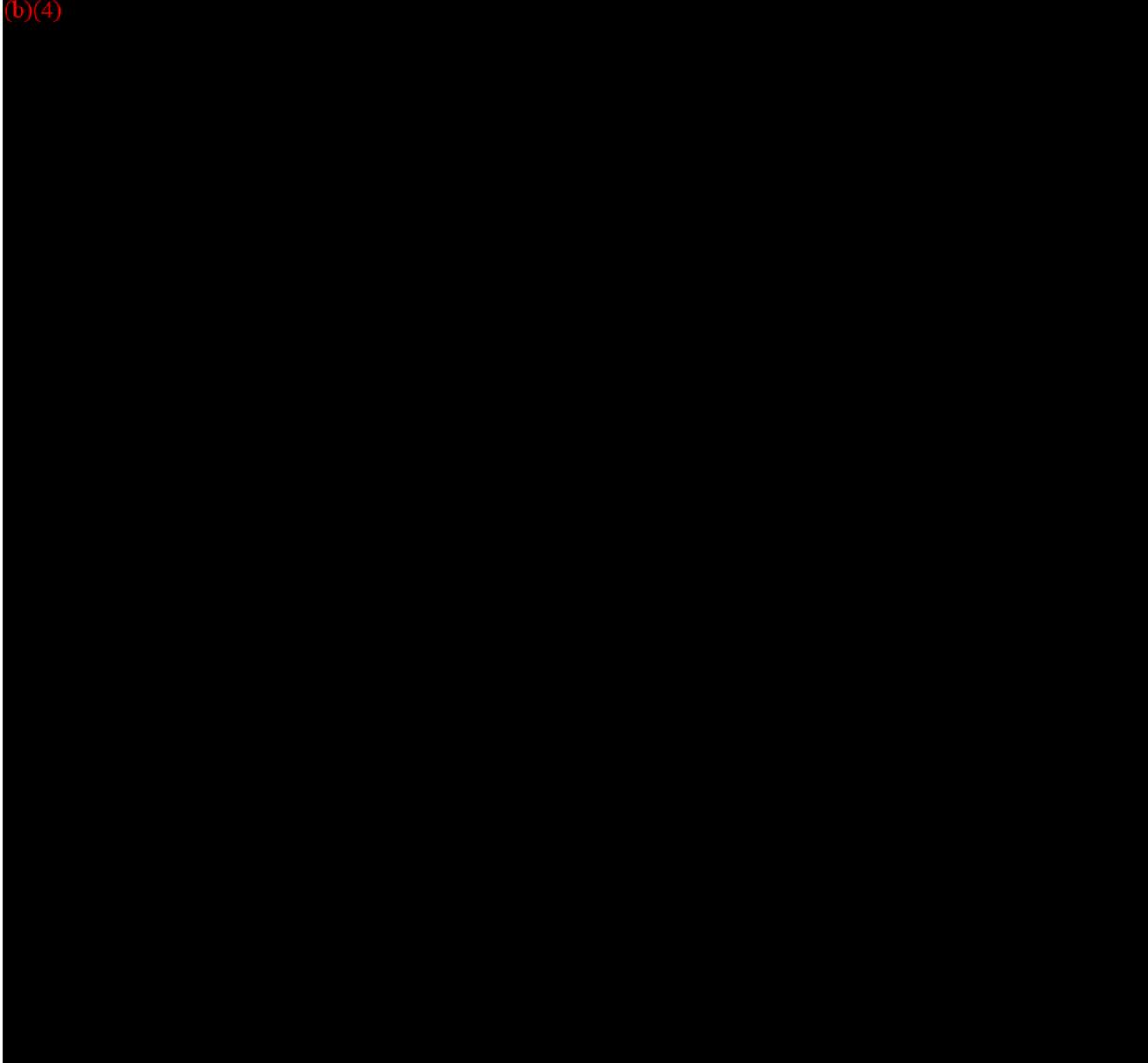
This response did not include a direct comparison to the predicate devices, since it had not been specifically stated in FDA's request for additional information. The direct comparison of the clinical effectiveness of the candidate device to those of the predicate devices was included (though based on VAS analysis) in Section 12 of the original submission.

4. *NSE letter dated December 3, 2008* – The clinical deficiency pointed out in the letter focuses on lesion resolution by day 5, specifically referring to lesions that are either fully or almost resolved. Publicly available data quantifying the performance of the predicate devices is included on Pg. 21D-5 of Section 21-D¹ for the Zeno™ system, and on Pg. 21H-1 of Section 21-H for the thermaclear™ system. These results contain data on fully resolved lesions², and therefore the following table compares the predicate devices' results on Day 5 to those of the candidate device. All the results are based on the evaluation of photographs by

(b)(4)



(b)(4)



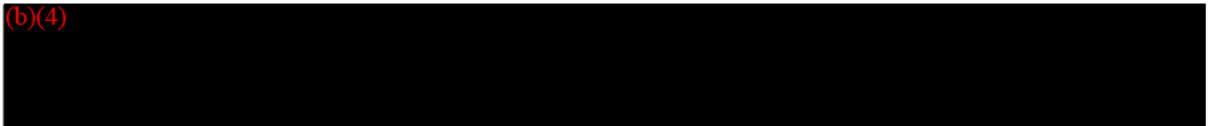
Please refer any communications regarding this request to: Zvi Ladin, Ph.D, Boston MedTech Advisors, Inc. 990 Washington Street, Suite 204, Dedham, MA 02026, Ph: (781) 407-0900 / x104, FAX: (781) 407-0901, Cell: (617) 921-6400, E-mail: zladin@bmtadvisors.com.

Sincerely yours,



Zvi Ladin, PhD, Principal, Boston MedTech Advisors, Inc., for
Dolev Rafaeli, CEO, Radiancy, Inc.

(b)(4)



Confidential

3

96

Rosecrans, Heather S.

From: Rosecrans, Heather S.
nt: Monday, January 05, 2009 1:22 PM
: Melkerson, Mark N.; Courtney, Michael
Cc: Tillman, Donna-Bea; Foreman, Christy
Subject: FW: No!No! Skin Device K082423.pdf - Adobe Acrobat Professional

Importance: High

Attachments: No!No! Skin Device K082423.pdf

Hi Mark,
Are you handling this appeal or does it need to go to Donna Bea? Thx.

Heather

Main Line (240) 276-4040
Direct Line (240) 276-4021
Fax (240) 276-4009
Heather.Rosecrans@FDA.HHS.gov

From: Lyons, Linda
nt: Monday, January 05, 2009 1:15 PM
o: Rosecrans, Heather S.
Subject: No!No! Skin Device K082423.pdf - Adobe Acrobat Professional



No!No! Skin Device
K082423.pdf...



December 18, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

DEC 19 2008

DEC 19 2008

Received

K21

Attn.: Mr. Mark Melkerson, Director, Division of General, Restorative and Neurological Devices, Office of Device Evaluation, Center for Devices and Radiological Health

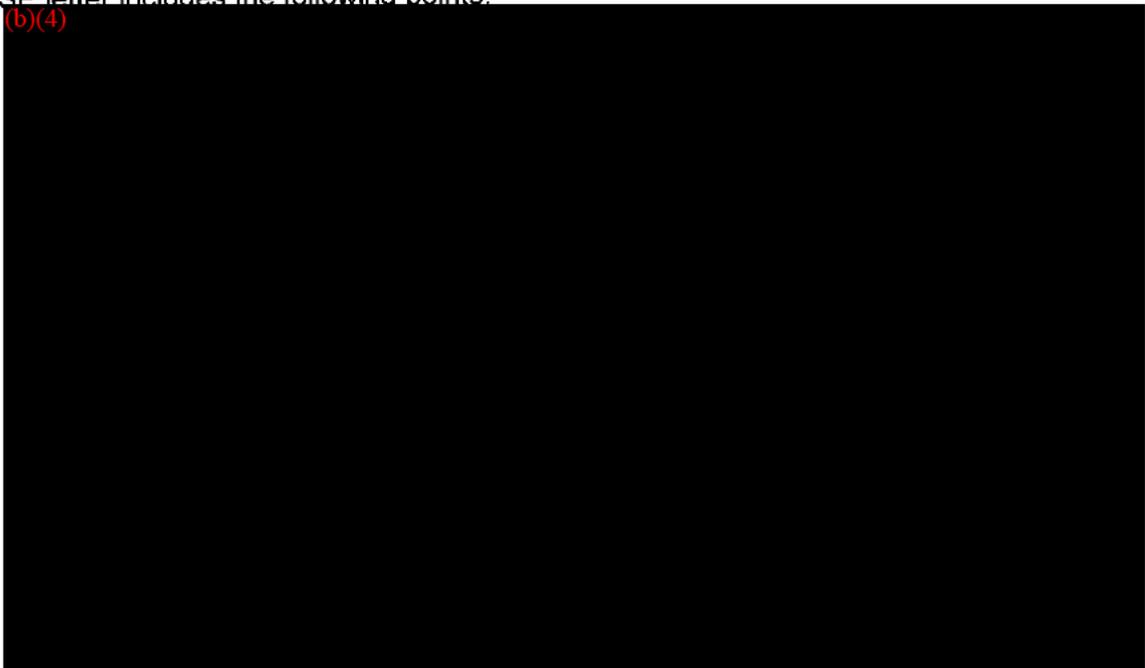
Re: 510(k) Premarket Notification for the no!no! Skin™ Device #K082423

Dear Mr. Melkerson:

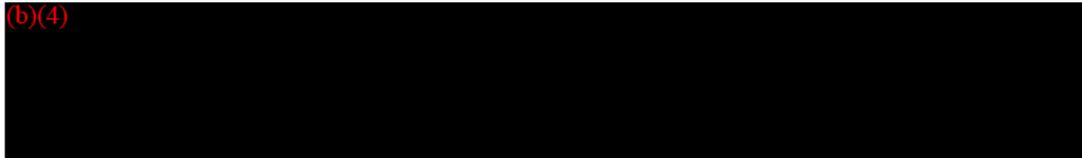
This letter is intended to elucidate information included in 510(k) pre-market notification #K082423, no!no! Skin™ Device. The sponsor of the submission, Radiancy (Israel), Ltd believes that due consideration of this information strongly supports the substantial equivalence claim of the device, and therefore respectfully requests the FDA to reconsider its Not Substantially Equivalent ('NSE') decision issued on December 3, 2008. The sponsor further requests to hold a meeting to discuss the clinical equivalence between the candidate and predicate devices, and to suspend the 30-day time limit for appealing FDA's decision, until this clarification process has run its course.

The NSE letter includes the following points:

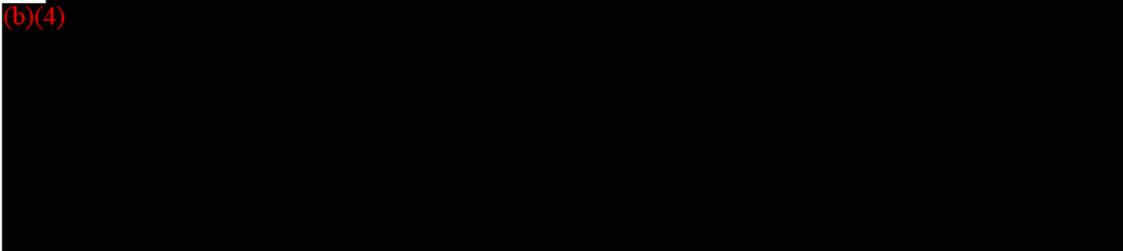
- 1.
- 2.



(b)(4)

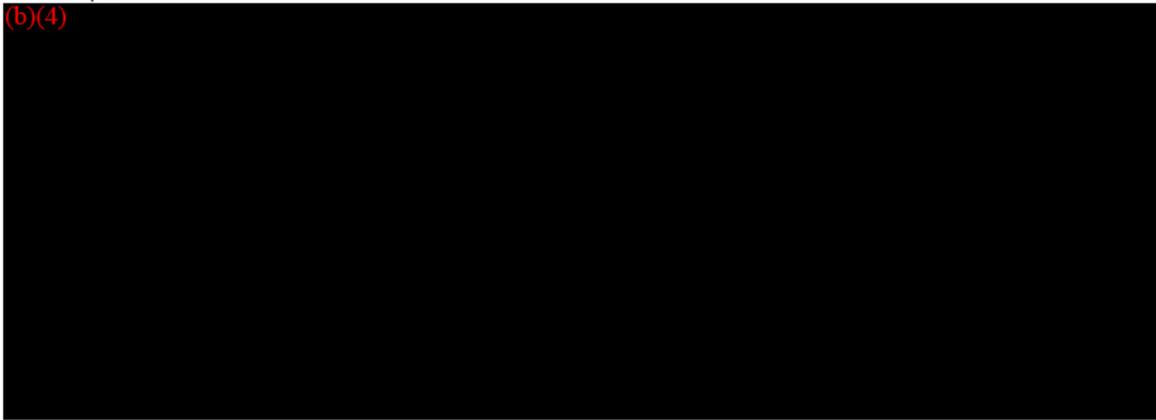
A large black rectangular redaction box covers the majority of the page content. To the left of the box, there are two bullet points.

(b)(4)

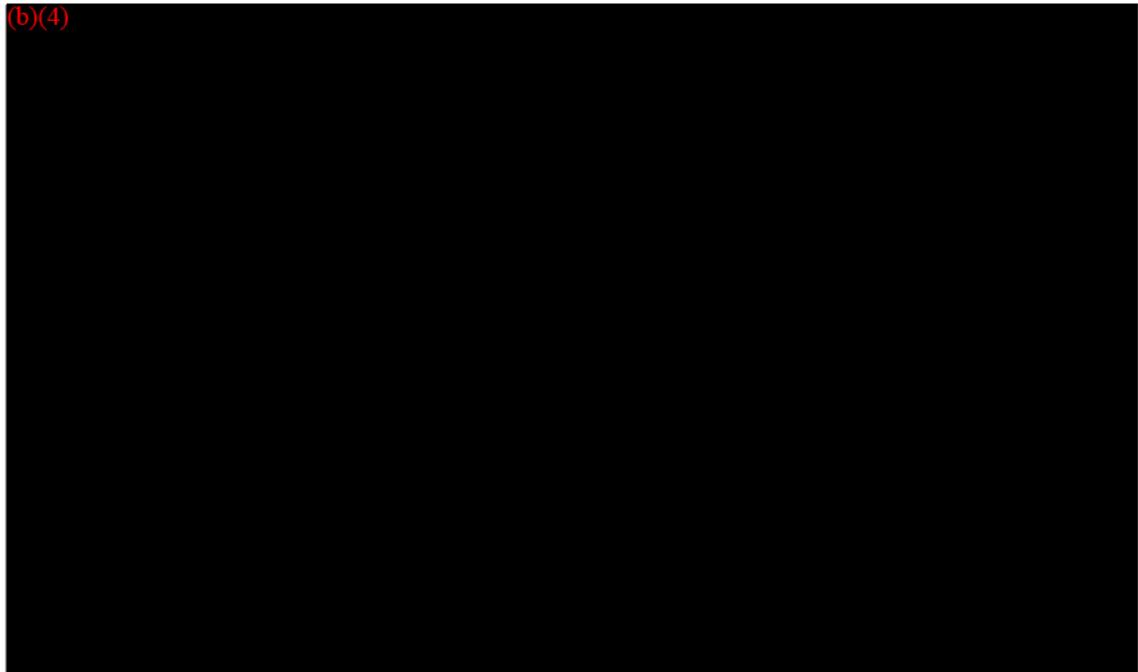
A large black rectangular redaction box covers the majority of the page content. To the left of the box, there are two bullet points.

3. *Data requested on October 21, 2008* – The letter issued by the FDA on October 21, 2008 included the following request:

(b)(4)

A large black rectangular redaction box covers the majority of the page content. To the left of the box, there are two bullet points.

(b)(4)

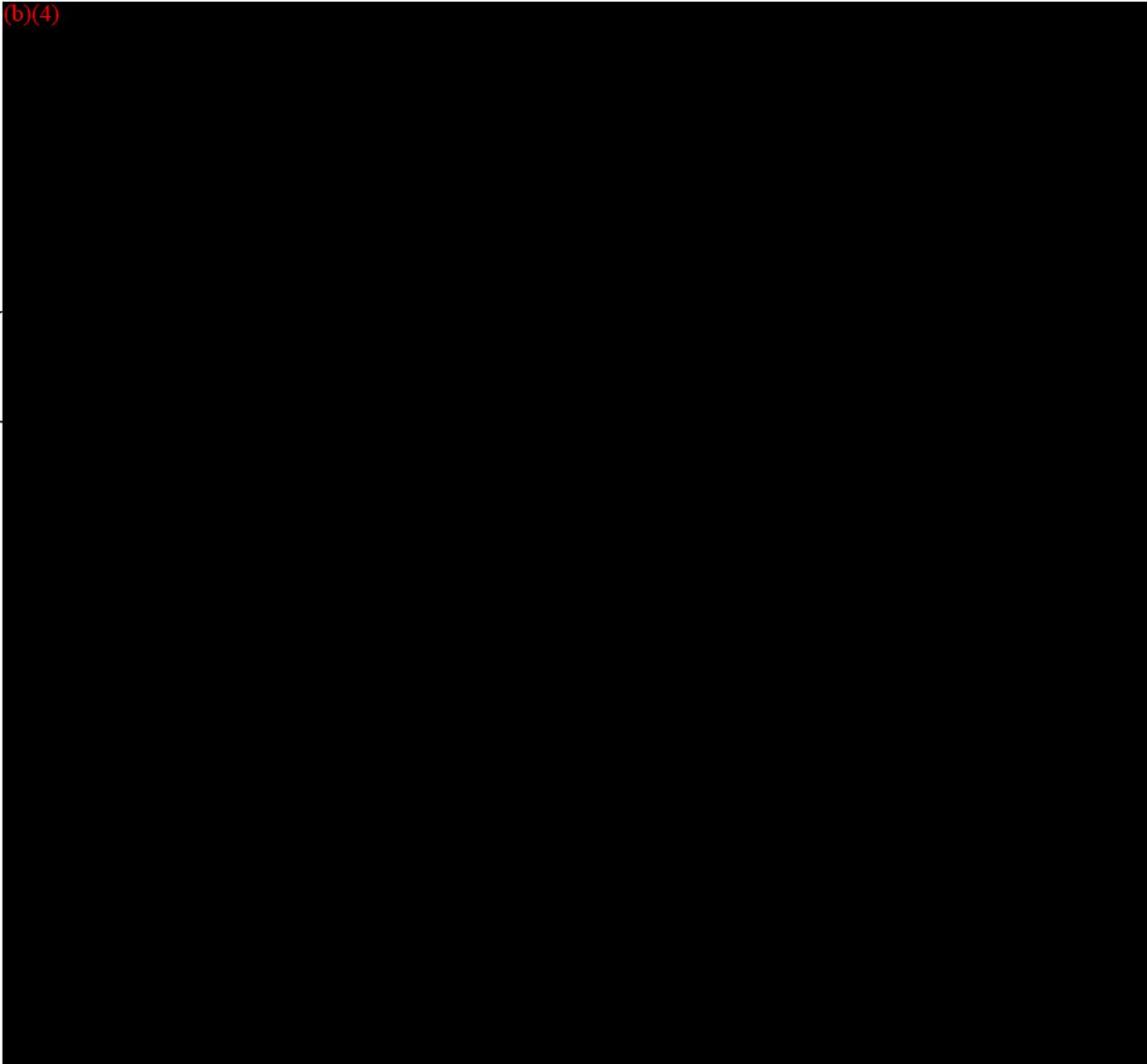
A large black rectangular redaction box covers the majority of the page content. To the left of the box, there are two bullet points.

4.

¹ All references to page and section numbers refer to the original submission.

² Zeno includes also data on 'improved' lesions, however, based on FDA's letter of October 21, 2008 "Improvement is not an endpoint we have used to support this indication". Therefore the above comparison is made only with respect to cleared lesions.

(b)(4)



Please refer any communications regarding this request to: Zvi Ladin, Ph.D, Boston MedTech Advisors, Inc. 990 Washington Street, Suite 204, Dedham, MA 02026, Ph: (781) 407-0900 / x104, FAX: (781) 407-0901, Cell: (617) 921-6400, E-mail: zladin@bmtadvisors.com.

Sincerely yours,



Zvi Ladin, PhD, Principal, Boston MedTech Advisors, Inc., for
Dolev Rafaeli, CEO, Radiancy, Inc.

³ These results were originally included in Tables 14 (Pg. 24 of 29) and 15 (Pg. 25 of 29) of Section 20-F of the original submission. They were also duplicated in the correspondence dated October 23, 2008.

Confidential

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 03 2008

Radiancy (Israel) LTD.
% Boston MedTech Advisors, Inc.
Zvi Ladin, PhD
990 Washington Street, Suite 204
Dedham, Massachusetts 02026

Re: K082423
Trade Name: no!no! Skin™
Regulatory Class: III
Product Code: GEX
Dated: October 23, 2008
Received: October 24, 2008

Dear Dr. Ladin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We have determined the device is not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to any device which has been reclassified into class I (General Controls) or class II (Special Controls), or to another device found to be substantially equivalent through the 510(k) process. This decision is based on the fact that the performance data you have provided on September 25, 2008 and October 11, 2008 did not demonstrate your device to be as safe and effective as legally marketed devices.

You may resubmit a new 510(k) if you have data you believe can show your device to be substantially equivalent.

Therefore, this device is classified by statute into class III (Premarket Approval), under Section 513(f) of the Federal Food, Drug, and Cosmetic Act (Act).

Section 515(a)(2) of the Act requires a class III device to have an approved premarket approval application (PMA) before it can be legally marketed, unless the device is reclassified.

Any commercial distribution of this device prior to approval of a PMA, or the effective date of any order by the Food and Drug Administration re-classifying this device into class I or II, would be a violation of the Act. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

If you wish to pursue the marketing of this device and need information or assistance for preparing investigational or premarket submissions, please contact the Division of Small

Page 2 – Zvi Ladin, PhD

Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address www.fda.gov/cdrh/industry/support/index.html.

If you decide to submit a new 510(k) you should submit a complete submission which includes the information identified in Title 21, Code of Federal Regulations (21 CFR), Section 807.87 and follows the formatting specified in 21 CFR, Section 807.90, and also refer to our document, titled Guidance for Industry and FDA Staff - Format for Traditional and Abbreviated 510(k)s which is available from the Internet at: www.fda.gov/cdrh/ode/guidance/1567.pdf. In addition, please ensure that any new 510(k) includes information that addresses the following issues:

In the original submission, you provided data in the form of the time to improvement and the time to resolution for acne vulgaris using the Visual Analog Scale (VAS) and the Photographic Lesion Reference Scale (PLRS). The VAS stated that the time to resolution data between the active device and placebo device was statistically insignificant, but the time to improvement data was significant. Because the use of the VAS scale could not, in our opinion, determine what is meant by improvement, we asked you on September 25, 2008 to provide the individual patient time to improvement data in terms of the PLRS to see if it could be compared to the predicate device's data which were based on time to resolution of the lesion. The additional information provided was not adequate to support substantial equivalence. On October 11, 2008 we requested that you provide data using the PLRS scale in terms of time to resolution which you stated you do possess. We requested that you use this PLRS scale time to resolution data to provide a direct comparison to the predicate device(s) that have been cleared for over-the-counter (OTC) usage. Unfortunately, the data you provided in your response does not provide sufficient evidence for a substantial equivalence determination to the predicate devices that have been cleared for OTC use. The reason for this failure is that by day 5 the OTC predicate devices were able to show complete resolution (the lesions were either fully resolved or almost resolved) of the lesions using the active device in their clinical study, while your device does not show complete resolution of the lesions.

The information requested above represents the issues that we believe need to be resolved before our review of a new 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies should you decide to submit a new 510(k). We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the document, "A Suggested Approach to Resolving Least Burdensome Issues". It is available on the Internet at www.fda.gov/cdrh/modact/leastburdensome.html.

Page 3 – Zvi Ladin, PhD

If you have any questions concerning the additional information that should be submitted in a new 510(k) submission, please contact Mr. Kareem Burney at (240) 276-3600.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2008

Radiancy (Israel) Ltd
% Boston Medtech Advisors
Zvi Ladin, PhD
990 Washington Street, Suite 204
Dedham, Massachusetts 02026

Re: K082423

Trade Name: No! No! Skin

Dated: October 2, 2008

Received: October 6, 2008

Dear Dr. Ladin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device because of an issue found in your submission. To complete the review of your submission, we require the following additional information:

1. In response to our AI Letter sent October 6, 2008, you provided information on how many individuals showed improvement based on the photographic lesion evaluation. The information you provided however is not enough to support substantial equivalence. The predicate devices that were granted the indication of "The treatment of individual acne pimples in a person with mild to moderate inflammatory acne" were evaluated based on time to resolution, not time to improvement. Improvement is not an endpoint we have used to support this indication. We are unsure what it means, and therefore cannot determine substantial equivalence. In order to receive the same indication as the predicate devices you will also have to provide a study where the primary endpoint of your study is the time to resolution. The result of this study has to show a statistically significant difference between lesions treated by the active and placebo devices.

Because you submitted the device for OTC use, we thank you for conforming your instructions for use to the format used in our OTC labeling guidance. Please note that we found numerous issues that need to be corrected to improve the effectiveness of the OTC labeling. Our OTC labeling review is on-going. When you respond to the critical issue above or sooner, we will contact you concerning the deficiencies in your OTC labeling.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

Page 2 – Mr. Zvi Ladin

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center web page at:
<http://www.fda.gov/cdrh/modact/leastburdensome.html>

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, “Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment”. If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Page 3 – Mr. Zvi Ladin

If you have any questions concerning the contents of the letter, please contact Kareem S. Burney at (240) 276-4100. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Neil R.P. Ogden, M.S.
Chief, General Surgery Devices
Branch
Division of General, Restorative
and Neurological Devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

September 25, 2008

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40)
9200 Corporate Blvd.
Rockville, Maryland 20850

RADIANCY (ISRAEL) LTD.
C/O BOSTON MEDTECH ADVISORS
990 WASHINGTON ST.
DEDHAM, MA 02026
ATTN: DR. ZVI LADIN

510(k) Number: K082423
Product: NO!NO! SKIN

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(1)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

39

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 22, 2008

RADIANCY (ISRAEL) LTD.
C/O BOSTON MEDTECH ADVISORS
990 WASHINGTON ST.
DEDHAM, MA 02026
ATTN: DR. ZVI LADIN

510(k) Number: K082423
Received: 22-AUG-2008
Product: NO!NO! SKIN

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. ' 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued

a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review:

- 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process.
- 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240) 276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K082423

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No!no! Skin™

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RADIANCY (ISRAEL) LTD. no!no! Skin™

510(k) PREMARKET NOTIFICATION CHECKLIST

<u>ITEM</u>		<u>COMMENT</u>
1.	Device trade or proprietary name	See 510(k) Cover Letter, Section 3(1a) – no!no! Skin™
2.	Device common or usual name or classification name	See 510(k) Cover Letter, Section 3(1b) – Pulsed Light System
3.	Establishment registration number (only applies if establishment is registered)	See 510(k) Premarket Review Submission Cover Sheet, Section 2(B) - 9616256
4.	Class into which the device is classified	See 510(k) Cover Letter, Section 3(5) - this is a Class II device
5.	Classification Panel	See 510(k) Cover Letter, Section 3(5) – General and Plastic Surgery Devices Branch
6.	Action taken to comply with Section 514 of the Act	See 510(k) notice Section 9 – Not applicable - no performance standards developed and no applicable special controls
7.	Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use	See 510(k) notice Section 13
8.	A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	See 510(k) notice Section 5
9.	For class III devices only, a class III certification and a class III summary	Not applicable .this is not a class III device
10.	Photographs and engineering drawings of the device	See 510(k) notice Section 11
11.	The marketed device(s) to which equivalence is claimed including labeling and description of the device	See 510(k) notice Sections 12, 21
12.	Statement of similarities and/or differences with marketed devices(s)	See 510(k) notice Section 12
13.	Data to show consequences and effects of a modified device	Not applicable

No!no! Skin™

14.	Submitter's name and address	See 510(k) Cover Letter, Section 3(2)
15.	Contact person, telephone number and fax number	See 510(k) Cover Letter, Section 3(3)
16.	Representative/Consultant if applicable	Zvi Ladin Regulatory Consultant Boston MedTech Advisors
17.	Table of Contents with pagination	See 510(k) notice page 1
18.	Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	See 510(k) Premarket Review Submission Cover Sheet, Section 2(H)
19.	Comparison table of the new device to the marketed device(s)	Not applicable
20.	Action taken to comply with voluntary standards	See 510(k) notice, Section 17
21.	Performance data	
	a. marketed device	Not applicable
	1. bench testing	
	2. animal testing	
	3. clinical data	
	b. new device	
	1. bench testing	See 510(k) notice Section 18
	2. animal testing	Not applicable
	3. clinical data	See 510(k) notice Section 20
22.	Sterilization information	Not applicable – See 510(k) notice Section 14
23.	Software Information	See 510(k) notice Section 16
24.	Hardware Information	See 510(k) notice section 11
25.	Is this device subject to issues that have been addressed in specific guidance document(s)?	Not applicable
26.	Indications for Use Statement	See 510(k) notice Section 4
27.	Biocompatibility Certification	See 510(k) notice Section 15
28.	Financial Certification or Disclosure	See 510(k) notice Section 8
29.	Truthful and Accurate Statement	See 510(k) notice Section 6
30.	Other (specify)	Not applicable

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
---	---

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/mdufma/cover sheet.html>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) RADIANCY ISRAEL LTD 990 WASHINGTON STREET SUITE 204 Dedham MA 02026 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) NO DATA	2. CONTACT NAME Zvi Ladin 2.1 E-MAIL ADDRESS zladin@bmtadvisors.com 2.2 TELEPHONE NUMBER (include Area code) 7814070900 2.3 FACSIMILE (FAX) NUMBER (Include Area code) null-7814070901
---	---

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/dc/mdufma>)

Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
---	--

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
---	--

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 13-Aug-2008

Online Payment

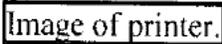
Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

It is recommended you print a copy for your records.

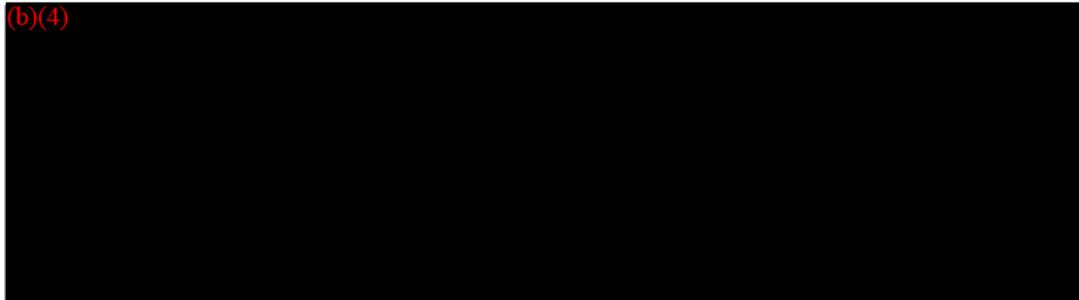
 Print this window.

Pay.gov Tracking Information

Application Name: FDA User Fees
 Pay.gov Tracking ID: 24UTFL0F
 Agency Tracking ID: 6038002
 Transaction Date and Time: 08/14/2008 13:09 EDT

Payment Summary

Account Holder Name:



Payment Amount:

Account Type:

Routing Number:

Account Number:

Check Number:

[Return to your agency website](#)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.
Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)

SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Radiancy (Israel) Ltd.		Establishment Registration Number (if known) 9616256	
Division Name (if applicable) N/A		Phone Number (including area code) (972) 8-943-8010	
Street Address 9 Gan Rave Street, Industrial Park		FAX Number (including area code) (972) 8-943-8020	
City Yavne	State / Province N/A	ZIP/Postal Code 81223	Country ISRAEL
Contact Name Dr. Dolev Rafaeli			
Contact Title CEO		Contact E-mail Address dolev@radiancy.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name Boston MedTech Advisors		Phone Number (including area code) (781) 407-0900	
Division Name (if applicable) N/A		FAX Number (including area code) (781) 407-0901	
Street Address 990 Washington Street		FAX Number (including area code) (781) 407-0901	
City Dedham	State / Province MA	ZIP/Postal Code 02026	Country USA
Contact Name Dr. Zvi Ladin			
Contact Title Principal		Contact E-mail Address zladin@bmtadvisors.com	

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (specify):

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Reponse to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		

Other Reason (specify):

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
--	---	---

Other Reason (specify):

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GEX	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- 510 (k) summary attached
 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K032205	1	ClearTouch™	1	Radiancy Ltd
2	K043377	2	Zeno™	2	Tyrell, Inc.
3	K060653	3	ThermaClear™	3	DermaCare, Inc.
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	no!no! Skin™	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code GEX	C.F.R. Section (if applicable) 21 CFR §878.4810	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel		

Indications (from labeling)

no!no! Skin™ is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 9616256	
		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Radiancy (Israel) Ltd.		Establishment Registration Number 9616256	
Division Name (if applicable) N/A		Phone Number (including area code) (972) 8-934-8010	
Street Address 9 Gan Rave Street, Industrial Park		FAX Number (including area code) (972) 8-934-8020	
City Yavne		State / Province N/A	ZIP/Postal Code 81223 Country ISRAEL
Contact Name Dr. Dolev Rafaeli		Contact Title CEO	Contact E-mail Address dolev@radiancy.com
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code Country
Contact Name		Contact Title	Contact E-mail Address
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code Country
Contact Name		Contact Title	Contact E-mail Address

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SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	IEC 60601-1:1988	IEC	Medical Electrical Equipment -- Part 1: General Requirements for Safety	1988+A1:1991+A2:1995	01/01/1988
2	Standards No. EN 60601-1-2:2001	Standards Organization	Standards Title EMC	Version	Date 01/01/2001
3	Standards No. IEC 61000-4-2:2001	Standards Organization IEC	Standards Title EMC	Version	Date 01/01/2001
4	Standards No. CISPR 11:2004, Class B	Standards Organization	Standards Title EMC	Version Amendment A2:2006	Date 01/01/2006
5	Standards No. IEC 61000-4-3:2006	Standards Organization IEC	Standards Title EMC	Version	Date 01/01/2006
6	Standards No. IEC 61000-4-4:2004	Standards Organization IEC	Standards Title EMC	Version	Date 01/01/2004
7	Standards No. IEC 61000-4-6:2006	Standards Organization IEC	Standards Title EMC	Version	Date 01/01/2006

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control



August 21, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

AUG 27 2008

Attn.: Division of General, Restorative and Neurological Devices
Plastic and Reconstructive Surgery Devices Branch

Re: 510(k) Premarket Notification for the no!no! Skin™ Device

Dear Sir / Madam:

In accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act, Radiancy (Israel) Ltd. ("Radiancy") submits this traditional premarket notification to provide notice of its intent to market a new device, the no!no! Skin Device, as described in Section 4 (Indications for Use Statement).

1. Device Name

- a. Trade/Proprietary Name – no!no! Skin™
- b. Common Name – Pulsed Light System
- c. Classification Name – Laser surgical instrument for use in general and plastic surgery and in dermatology (21 C.F.R. § 878.4810).

2. Name and Address of Applicant

Radiancy (Israel), Ltd.
9 Gan Rave Street
Industrial Park
Yavne 81223
Israel

3. Contact Person and Phone/Fax Numbers

Zvi Ladin, Ph.D.
Principal, Boston MedTech Advisors
Telephone: 781-407-0900 / X104
Fax: 781-407-0901

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4. Confidentiality Statement

Radiancy considers its intent to market the no!no! Skin device as confidential commercial information and has taken precautions to protect the confidentiality of the intent to market the new device. The Company therefore requests FDA not to disclose the existence of this submission until such time as final action on the submission is taken. In addition, some of the material in this submission may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

5. Device Classification / Classification Panel

The no!no! Skin™ system is classified as a Class II laser surgical instrument pursuant to 21 C.F.R § 878.4810 and is reviewed by the General and Plastic Surgery Devices Branch.

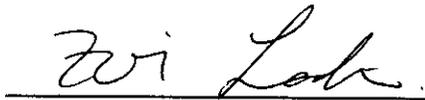
6. Product Code

The Product Code for the No!no! Skin™ device is GEX.

no!no! Skin is substantially equivalent to its predicate devices, namely, the Acne System with ClearTouch™ Light Unit Assembly manufactured by Radiancy (Israel) Ltd of Israel, cleared under 510(k) #K032205 on December 11, 2003, Zeno™ Acne Treatment System manufactured by Tyrell, Inc., cleared under 510(k) #K043377 on June 1, 2005 and the ThermaClear™ Acne Treatment Device manufactured by DermaCare, Inc., cleared under 510(k) #K060653 on October 24, 2006.

Please refer any communications regarding this application to: Zvi Ladin, Ph.D, Boston MedTech Advisors, Inc. 990 Washington Street, Suite 204, Dedham, MA 02026, Ph: (781) 407-0900 / x104, FAX: (781) 407-0901, Cell: (617) 921-6400, E-mail: zladin@bmtadvisors.com.

Sincerely yours,



Zvi Ladin, PhD, Principal, Boston MedTech Advisors, Inc., for
Dolev Rafaeli, CEO, Radiancy, Inc.

Indications for Use

510(k) Number (if known):

Device Name: no!no! Skin™

Indications For Use: no!no! Skin™ is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _____

510 (k) SUMMARY

Radiancy Ltd.'s no!no! Skin™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Manufacturer: Radiancy (Israel) Ltd.
9 Gav Rave Street
Industrial Park
Yavne
Israel
Telephone: +972-8-9438010
Facsimile: +972-8-9438020

Contact Person: Zvi Ladin, PhD.
Principal
Boston MedTech Advisors, Inc.
990 Washington Street
Suite #204
Dedham, MA 02026
Telephone: (781) 407 0900 x104
Facsimile: (781) 407 0901
Email: zladin@bmtadvisors.com

Date Prepared: August 20, 2008

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: no!no! Skin™

Common Name: Pulsed Light System

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 C.F.R. § 878.4810)

Manufacturing Facility: Radiancy (Israel) Ltd.
9 Gan Rave Street
Industrial Park
Yavne, Israel

Establishment
Registration Number: 9616256

Owner/operator number: 9040071

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Radiancy no!no! Skin Device™ 510(k) Submission
Section 5 – 510(k) Summary (public)

Page 1 of 2

Predicate Devices

ClearTouch™ Light Unit Assembly by Radiancy Ltd of Israel (#K032205), Zeno™ Acne Treatment System by Tyrell, Inc. (#K043377) and ThermaClear™ Acne Treatment Device by DermaCare, Inc. (#K060653).

Intended Use / Indications for Use

no!no! Skin™ is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Technological Characteristics

no!no! Skin is a portable, hand-held device that emits Light and Heat Energy (LHE®) intended to treat mild to moderate inflammatory acen. The biocompatible treatment tip is applied to the lesion, and the activation of the device delivers a series of short pulses of light to the acne lesion. The device is powered by a rechargeable battery.

Performance Data

Non-clinical and clinical performance testing was conducted. Non-clinical testing included compliance with electrical safety and electromagnetic interference standards. Clinical testing included a randomized, placebo-controlled, double-masked study.

Substantial Equivalence

no!no! Skin has the same intended use and indications for use, principles of operation and technological characteristics as the predicate devices. The slight differences between the device and its predicate devices do not raise new issues of safety and effectiveness.

Confidential and Proprietary Information

Radiancy no!no! Skin Device™ 510(k) Submission
Section 5 – 510(k) Summary (public)

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR 807.87(k))

I certify that, in my capacity as the president of Radiancy (Israel) Ltd., I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the no!no! Skin™ System are truthful and accurate and that no material fact has been omitted.



(Signature)

Dr. Dolev Rafaeli, President

Radiancy (Israel) Ltd.

August 21, 2008

www.radiancy.com

9 Gan Rave Avenu, Yavne 81223, Israel Tel: +972 8 943 3100 Fax: +972 8 942 8020

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7. Class III Summary and Certification

No!no! Skin is a Class II device and therefore this section is not applicable

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS	Form Approved: OMB No. 0910-0396 Expiration Date: April 30, 2009
---	---

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkboxes

(1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

(b)(4)

(2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

(3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Dr. Rafael Dolev	TITLE CEO
FIRM/ORGANIZATION RADIANCY	
SIGNATURE 	DATE 08/20/2008

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address in the right.

Department of Health and Human Services
 Food and Drug Administration
 5600 Fishers Lane, Room 14C-03
 Rockville, MD 20857

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9. Section 9 – Declaration of Conformity and Summary Reports

Certificates of conformity with electrical safety and electromagnetic compatibility standards and summary reports are included in Section 17.

Declaration of conformity with biocompatibility standards is provided in Section 15.

10. Executive Summary

The subject of this 510(k) premarket notification is the no!no! Skin™ device, manufactured by Radiancy, Ltd. The device is intended for over the counter (OTC) use, and is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

no!no! Skin is a small, portable, 6 VDC battery-powered, hand-held device. The device consists of an enclosure, a rechargeable battery, an electronic circuit and a low voltage halogen lamp. The no!no! Skin treatment cycle delivers a series of broad spectrum light pulses to a single acne lesion. The energy delivered to the lesion is a combination of focused light emitted from the halogen lamp together with heat accumulated in the chamber placed over the acne lesion.

Substantial equivalence is claimed to a combination of the following devices:

1. ClearTouch™ Light Unit Assembly by Radiancy Ltd of Israel (#K032205)
2. Zeno™ Acne Treatment System by Tyrell, Inc. (#K043377) and
3. ThermaClear™ Acne Treatment Device by DermaCare, Inc. (#K060653)

Table 1 summarizes the basic characteristics of the three predicate systems. They all treat the lesions by delivering either heat or a combination of light and heat (HLE™) to the target lesions, just as the no!no! Skin system does. Zeno and ThermaClear are small, light, hand-held, portable, battery powered devices designed to treat individual acne pimples, just as no!no! Skin. The ClearTouch Lite™ device has a larger light source requiring higher power input, provided by an AC power source. Its larger spot size allows the treatment of a larger skin area, potentially targeting a few pimples at a time. Both no!no! Skin and ClearTouch deliver the same fluence to the skin. Therefore, the technological characteristics of the no!no! Skin device are substantially equivalent to those of the predicate devices in terms of power and energy delivered to the tissue, its physical dimensions and overall weight, its user interface and mode of operation.

Feature	no!no! Skin™	ClearTouch Lite™	Zeno™	ThermaClear™
FDA Clearance		K060411 Prescription	K043377 OTC	K060653 OTC
Intended Use	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne	Treatment of mild to moderate inflammatory acne in skin types I-VI	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne
Energy Source	Light & Heat (LHE), Halogen lamp	Light & Heat (LHE), Xenon lamp	Low level heat, 49.4° C. Heating element	Nichrome heat element
Wavelengths	450-2000 nm	430-1100nm	NA	NA
Energy delivery duration	10 sec	6 sec	2.5 min	2 sec
Spot size	8 mm dia. 50 mm ²	27x14 mm	0.25 in (71 mm ²)	0.5 in (127 mm ²)
Max fluence	6 J/cm ²	6 J/cm ²	NA	NA
Electical input	Rechargeable batteries	110 VAC, 60 Hz	Rechargeable batteries	2 AA Batteries
Dimensions	145 X 36 X 26 mm	Not hand-held	114 X 38 X 13 mm	124 X 53 X 28 mm

Table 1. no!no! Skin™ Predicate Device Comparison

Radiancy Ltd. sponsored two studies designed to establish the usability of the device by uninitiated users and a two-site, randomized, placebo-controlled, double-blinded clinical trial designed to establish the safety and effectiveness of the device. (b)(4)

(b)(4)

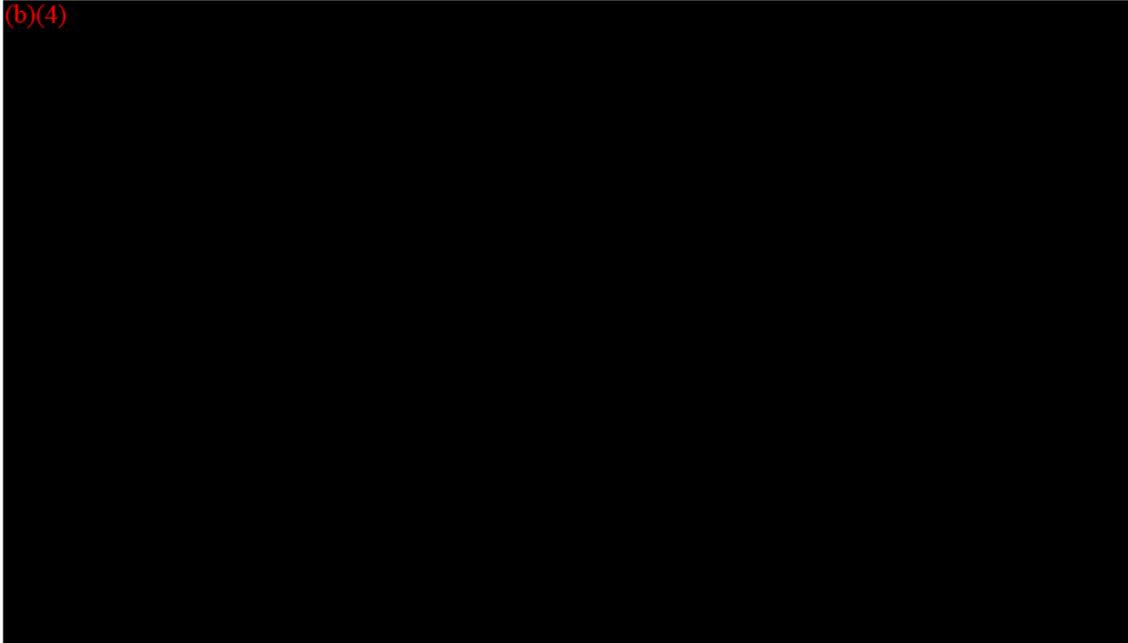
No!no! Skin™

(b)(4)

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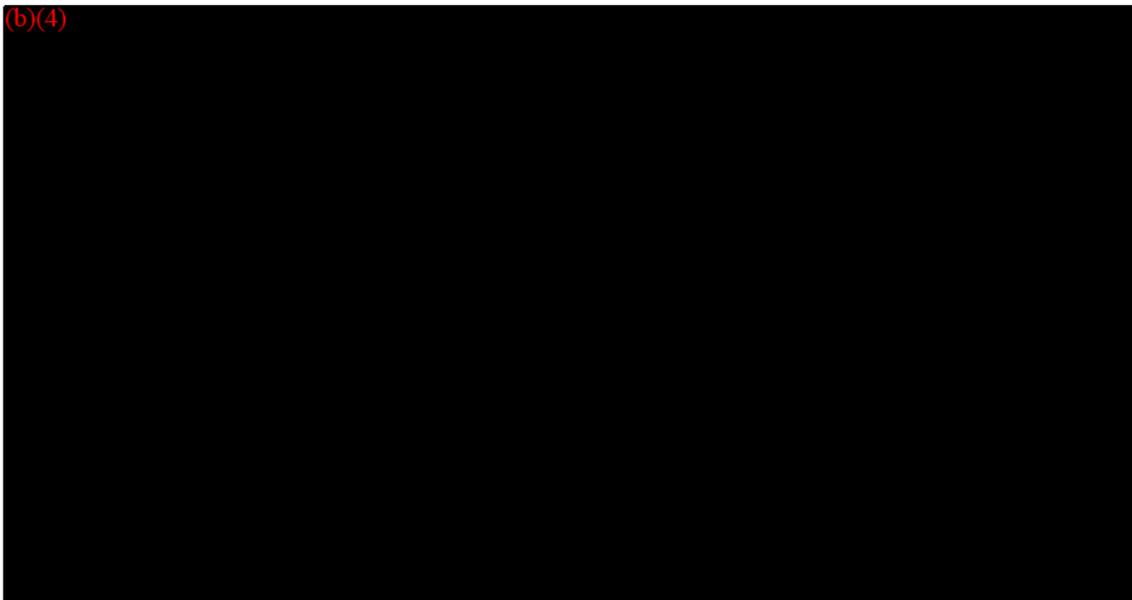
The protocol followed FDA's recommendations, resulting in the following observations:

- (b)(4)

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A clinical protocol was developed following discussions with the FDA regarding the main elements that that would be needed to establish the device's safety and effectiveness. The main elements of the protocol were:

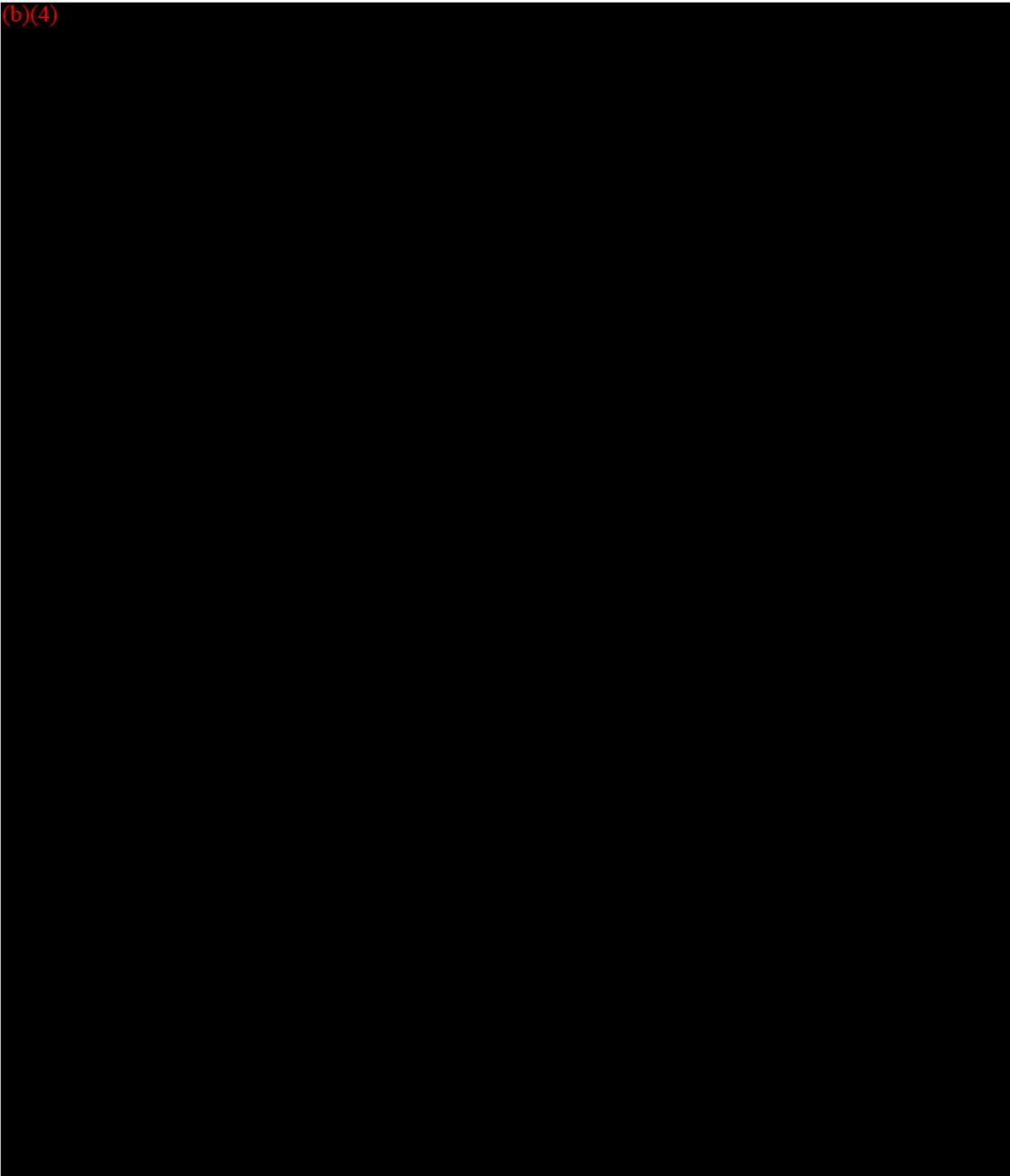
- (b)(4)

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The main results of the study are:

Confidential and Proprietary Information
Radiancy no!no! Skin Device™ 510(k) Submission
Section 10 – Executive Summary

No!no! Skin™



In conclusion, the clinical study documented the safety of the device, as evidenced by the single study-related minor adverse event. The study also documented the efficacy of the treatment due to the statistically significant shortening in both time to improvement and time to resolution of acne lesions in the Treatment arm.

A comparison to the clinical results demonstrated in similar studies with both OTC predicate devices is presented in Section 12. The results show remarkable similarity with almost identical values recorded for the reduction in time to improvement – 56% for no!no! Skin vs. 64% for Zeno, and similarly for the reduction in time to resolution – 38% for no!no! Skin vs. 36% for Zeno. The safety profile of all devices was almost identical with no treatment-related serious

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Radiancy no!no! Skin Device™ 510(k) Submission

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No!no! Skin™

adverse events, and only one minor adverse event (burning sensation) recorded in the no!no! Skin study. This adverse effect is listed as a possible effect to the treatment of all three predicate devices, and is widely accepted as a side effect of photothermal response of human skin when treated by pulsed light.

In summary, based on a comparison of the indications for use, the technological characteristics, the principles of operation, and the results of the user comprehension study and the clinical study the no!no! Skin device is concluded to be substantially equivalent to a combination of the above named predicate devices. The minor differences detailed in the discussion in Section 12 do not raise additional concerns of safety and efficacy.

11.A. no!no! Skin™ – Device Description Diagrams Sequence

The following diagrams of the no!no! Skin™ Device components are included in the appendix in the following order:

Device Description Diagrams Sequence Table

Document	Title	Sequence
3009690	No!No! Skin System	1
3009570	Assy Lamp and PCB for No!No! Skin	2
2020210	Reflector Halogen Lamp No!No! Skin	3
2020240	Operation SW Cap No!No! Skin	4
2020260	Lamp Protector No!No! Skin	5
2020290	Lamp Protector Cover No!No! Skin	6
2020250	Light Guide & Comp Cover No!No! Skin	7
2020230	Self-Adhesive Layer No!No! Skin	8
2020270	Front Cover No!No! Skin	9
2020280	Back Cover No!No! Skin	10
2020280	Back Cover No!No! Skin	11

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12. Substantial Equivalence Discussion

The no!no! Skin has the same intended use and the same indications for use as its predicate devices, namely, Zeno™ Acne Treatment System manufactured by Tyrell, Inc., cleared under 510(k) #K043377 on June 1, 2005 and the ThermaClear™ Acne Treatment Device manufactured by DermaCare, Inc., cleared under 510(k) #K060653 on October 24, 2006. It has similar indications for use and is based on the same technological characteristics as the Acne System with ClearTouch™ Light Unit Assembly manufactured by Radiancy (Israel) Ltd of Israel, cleared under 510(k) #K032205 on December 11, 2003.

Table 1 summarizes the basic characteristics of the three predicate systems. They all treat the lesions by delivering either heat or a combination of light and heat (HLE™) to the target lesions, just as the no!no! Skin system does. Zeno and ThermaClear are small, light, hand-held, portable, battery powered devices designed to treat individual acne pimples, just as no!no! Skin. The ClearTouch Lite™ device has a larger light source requiring higher power input, provided by an AC power source. Its larger spot size allows the treatment of a larger skin area, potentially targeting a few pimples at a time. Both no!no! Skin and ClearTouch deliver the same fluence to the skin. Therefore, the technological characteristics of the no!no! Skin device are substantially equivalent to those of the predicate devices in terms of power and energy delivered to the tissue, its physical dimensions and overall weight, its user interface and mode of operation.

Radiancy (Israel) Ltd sponsored two studies designed to establish the usability of the device by uninitiated users and a two-site, randomized, placebo-controlled, double-blinded clinical trial designed to establish the safety and effectiveness of the device. The study protocols, statistical reports and clinical summaries are provided in Section 20 of this submission. The main findings of the clinical study were that the time to improvement of a lesion treated by the active device was 56% shorter than a lesion treated by the placebo device. Similarly, the time to resolution was 38% shorter for a lesion in the Treatment arm compared to a lesion in the placebo arm. The ClearTouch system was cleared for marketing based on a controlled, multi-center clinical study that demonstrated a mean reduction of 60% in lesion count at the 12 week follow-up period, following a treatment protocol of eight treatments applied twice weekly for four weeks.

Feature	no!no! Skin™	ClearTouch Lite™	Zeno™	ThermaClear™
FDA Clearance		K060411 Prescription	K043377 OTC	K060653 OTC
Intended Use	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne	Treatment of mild to moderate inflammatory acne in skin types I-VI	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne	Treatment of individual acne pimples in persons with mild to moderate inflammatory acne
Energy Source	Light & Heat (LHE), Halogen lamp	Light & Heat (LHE), Xenon lamp	Low level heat, 49.4° C. Heating element	Nichrome heat element
Wavelengths	450-2000 nm	430-1100nm	NA	NA
Energy delivery duration	10 sec	6 sec	2.5 min	2 sec
Spot size	8 mm dia. 50 mm ²	27x14 mm	0.25 in (71 mm ²)	0.5 in (127 mm ²)
Max fluence	6 J/cm ²	6 J/cm ²	NA	NA
Electical input	Rechargeable batteries	110 VAC, 60 Hz	Rechargeable batteries	2 AA Batteries
Dimensions	145 X 36 X 26 mm	Not hand-held	114 X 38 X 13 mm	124 X 53 X 28 mm

Table 1. no!no! Skin™ Predicate Device Comparison

Details of the clinical studies performed by Tyrell (using Zeno) and Therative (using ThermaClear) are provided in Section 21 of this submission. The Zeno device was evaluated by a double blind, placebo controlled clinical trial on 51 subjects with mild to moderate acne. Subjects received three treatments on similar individual lesions with either an active or a placebo device, and were followed for 5 days. ThermaClear was evaluated by a clinical trial on 46 subjects with mild to moderate acne. For each participant, acne lesions on one side of the face were treated with the ThermaClear device once daily for 5 days, while lesions on the other side of the face were left untreated as controls. Evaluations were performed by 'blinded' evaluators, based on randomly presented

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 Radiancy no!no! Skin Device™ 510(k) Submission
 Section 12 – Substantial Equivalence Discussion

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photographs of the lesions. The no!no! Skin, Zeno and ThermaClear studies are summarized in Table 2.

		no!no! Skin™	Zeno™	ThermaClear™	Comments
Clinical Study Protocol	Randomized	(b)(4)	Yes (lesion)	No (comparison to untreated lesions)	
	Placebo		Yes	No	
	Number of Clinical Sites			1	
	Number of lesions		102	430	
	Duration of study [days]		14	5	
	Blinding		Double	Only evaluation	
	Evaluation		Photograph	Photograph	
	Treatment duration		150 s	2 s	
	Number of treatments		3	5	
	Number of patients		51	46	
	Number of Evaluators		2	2	
	Results	Reduction in time to improvement		64%	
Reduction in time to resolution			36%		ThermaClear – cleared after 4 days: ~44% of treated vs. 10% of untreated
Study-related minor adverse events			0	0	
	Study-related serious adverse events		0	0	

Table 2. Summary of clinical studies performed on no!no! Skin, Zeno and ThermaClear

It is clear from the table that the studies involved similar protocols, a similar number of subjects and similar evaluation processes. Although the study durations are slightly different, they extended over a period of ~1 – 2 weeks. (b)(4)

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(b)(4)

(b)(4)

no treatment-related serious adverse events, and only one minor adverse event (burning sensation) recorded in the no!no! Skin study. The user manual of ThermoClear describes such an effect as an expected side effect of the treatment:

“Our clinical trials indicated no major adverse reactions. Side effects that may occur include brief discomfort due to the heated pulse, redness, dryness or peeling of skin. After each treatment, you may see redness where the tip was applied. This is normal and should quickly fade away.”

Similarly, Zeno's user manual describes some side effects that might be associated with the treatment as:

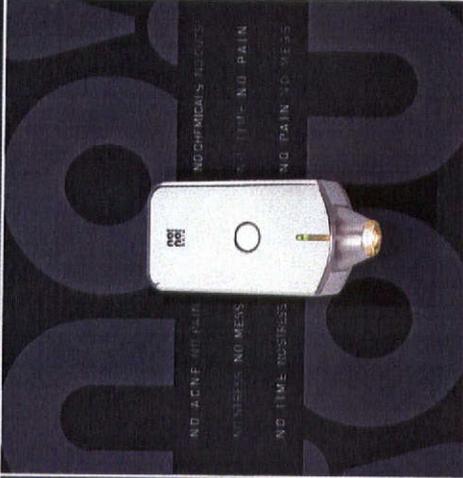
Clinical trials reported no major side effects. However, some side effects which might occur are brief soreness due to heat, brief skin redness, or dryness or peeling of skin.

In summary, based on a comparison of the indications for use, the technological characteristics, the principles of operation, and the results of the user comprehension study and the clinical study the no!no! Skin device is concluded to be substantially equivalent to a combination of the above named predicate devices. The minor differences detailed in the discussion above do not raise additional concerns of safety and efficacy.



The Healing Power of Light & Heat

Small, safe, effective and easy to use, the NO! Skin™ device is the first handheld, non-invasive, non-chemical, non-drug device to help you get rid of acne, wrinkles, and cellulite. It's the only device that uses a combination of light and heat to stimulate collagen production and improve skin texture. The NO! Skin device is safe, effective, and easy to use. It's the only device that uses a combination of light and heat to stimulate collagen production and improve skin texture.



NO! ACNE NO! PAIN
NO! WRINKLES NO! PAIN
NO! CELLULITE NO! PAIN

NO! SKIN™
Handheld Skin Treatment Device

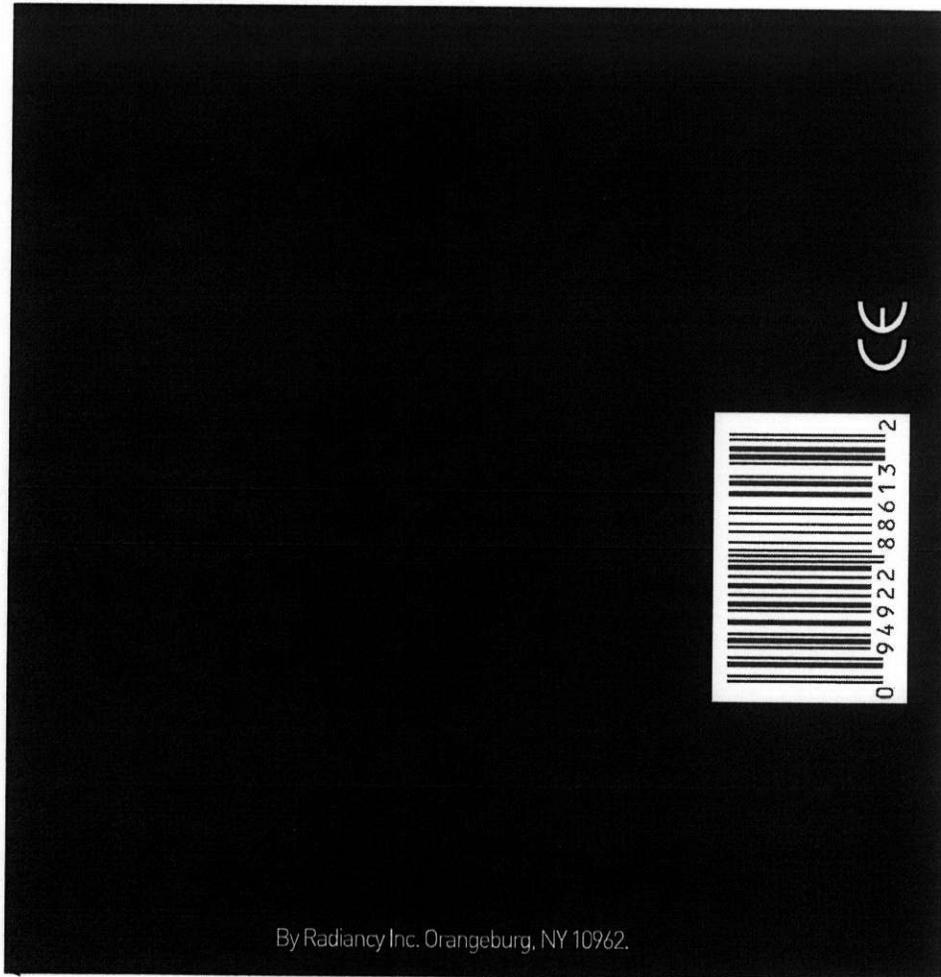
NO!
SKIN

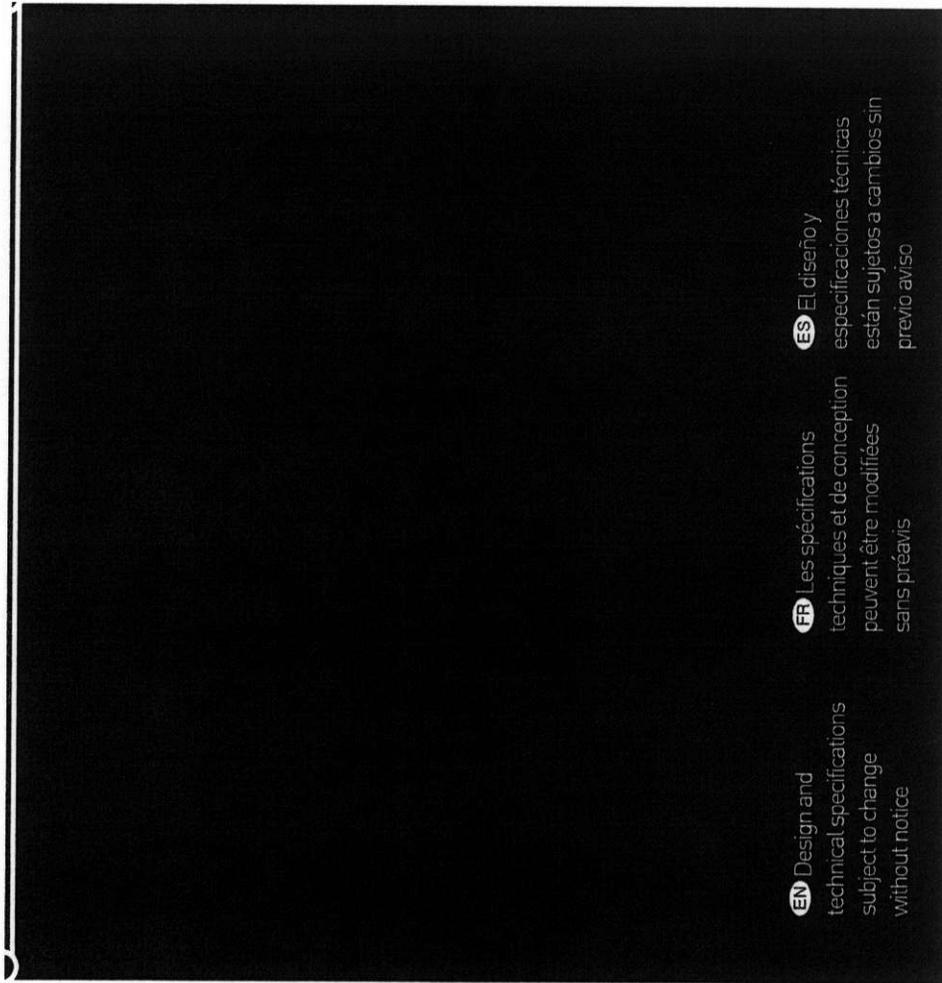


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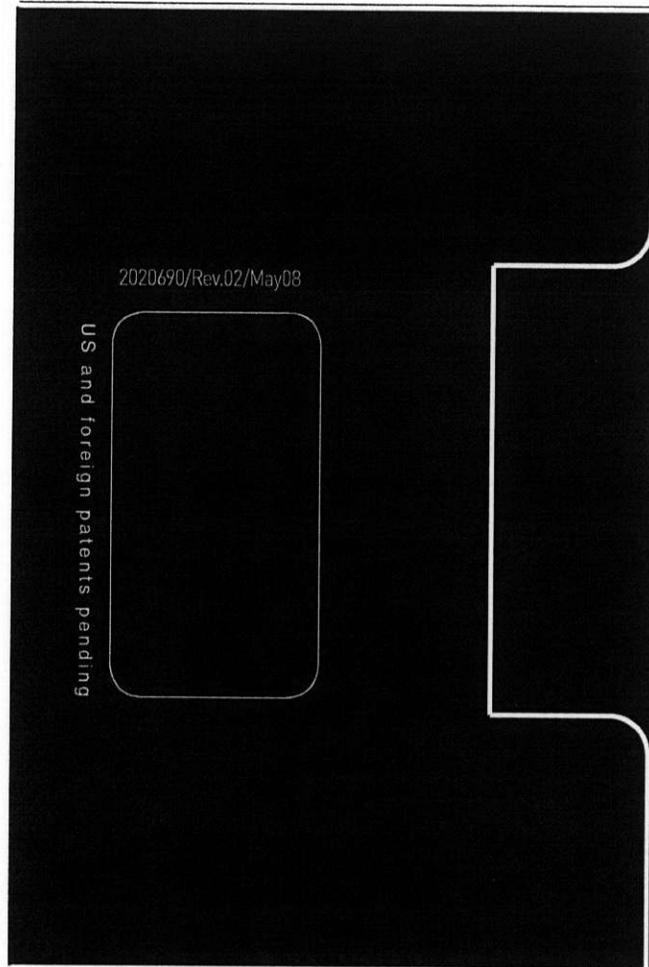


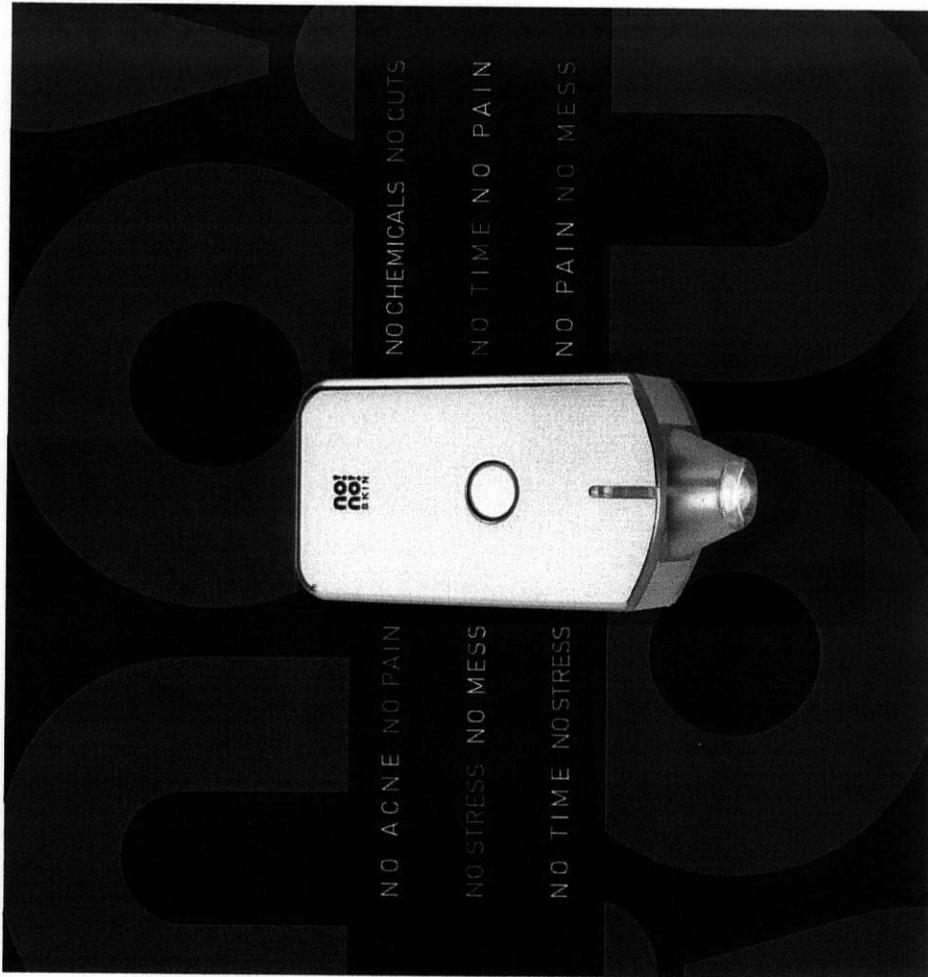


EN Design and technical specifications subject to change without notice

FR Les spécifications techniques et de conception peuvent être modifiées sans préavis

ES El diseño especificaciones técnicas están sujetos a cambios sin previo aviso







The Healing Power of Light & Heat

Small, light-weight and easy to use, no!no! Skin with LHE[®] technology painlessly stops pimples in their tracks. Trusted by doctors and skin care professionals around the world, LHE technology safely and effectively treats all skin colors with no burning or scarring. Enjoy the same care as a combination of Light and Heat pulses target and eliminate pimples at their source.

There are no chemicals and no medications. Simply place no!no! Skin over a pimple, push the button and in 10 seconds, you are on your way to clearer, cleaner and healthier looking skin.

no!no!Skin is clinically proven to be effective.



no!no! Skin™ User Manual

Instructions for Use & Technical Description

Professional acne treatment for personal use

July 2008

2018590 - Revision 04

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Radiancy no!no! Skin Device™ 510(k) Submission

Section 13 – Proposed Labeling (User Manual)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Radiancy no!no! Skin Device™ 510(k) Submission

Section 13 – Proposed Labeling (User Manual)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Safety Instructions

Electrical Safety

As with any electrical device, certain precautions are necessary in order to ensure your safety.

READ ALL INSTRUCTIONS BEFORE USING **no!no! Skin**. ALL WARNING AND CAUTIONS SHOULD BE STRICTLY FOLLOWED.

DANGER – to reduce risk of serious injury from electrical shock:

- Do not reach for **no!no! Skin** if it has fallen into the water during charging. Unplug the charger immediately.
- Do not place or store **no!no! Skin** near a sink or bathtub.
- Do not place in or near water or other liquids.
- Always unplug **no!no! Skin** from its charger before use, cleaning or maintenance.

WARNING & PRECAUTIONS – To reduce the risk of burns, fire, electrical shock or injury.

- Use **no!no! Skin** for its intended use as described in this manual.
- Keep out of reach of children.
- **no!no! Skin** may be used by the ages 14 years and older.
- Do not submerge in water or allow **no!no! Skin** to become wet in anyway,
- Do not use **no!no! Skin** or the charger if they are damaged in anyway, do not work properly, or were dropped into water and are wet. Return the damaged part to a service center for examination and/or repair.
- Only use **no!no! Skin** with its original charger.
- Do not use an extension cord with the charger.
- Keep inflammable away from inflammable environments and hot surfaces such as stoves and radiators.

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Radiancy **no!no! Skin Device™** 510(k) Submission

Section 13 – Proposed Labeling (User Manual)

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- Do not use **no!no! Skin** near or rest it on flammable objects such as paper, cloth, etc.
- Do not open the outer casing of **no!no! Skin**. This will void your warranty and may damage the unit.

CAUTIONS

- If you have any skin condition, consult your doctor before using **no!no! Skin**.
- Do not use **no!no! Skin** if you have been using Accutane or any photosensitizing medications in the past 6 months. Check the medication label and/or consult your doctor.
- Do not use **no!no! Skin** if you suffer from epilepsy.
- Consult your physician before using **no!no! Skin** if you are pregnant or nursing.
- Do not use **no!no! Skin** if you were exposed to strong sunlight or an artificial tanning device in the past month.
- Do not use **no!no! Skin** if you have an active implant, such as a pacemaker, incontinence device, insulin pump, etc.
- Do not use **no!no! Skin** on sunburned skin, rashes, open cuts and sores, bruises, blisters, moles birthmarks, pigmented lesions - like sun spots, age spots and raised areas such as scars.
- **no!no! Skin** is for personal use only.
- Do not look directly at the light coming from the opening.
- Do not use **no!no! Skin** on or near the eyes.
- Do not point **no!no! Skin** so it emits a light pulse into the air.
- Always keep the treatment tip pointed at and in full contact with the skin during pulsing.
- If, during the pulse sequence, **no!no! Skin** feels too hot, remove it immediately from your skin and allow it to cool.

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Radiancy no!no! Skin Device™ 510(k) Submission

Section 13 – Proposed Labeling (User Manual)

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- Stop treatment if you experience significant redness of the skin, blistering or burns.
- In case of burns, apply first aid treatment.
- Before using **no!no! Skin**, make sure your skin's surface is completely dry: no deodorants, no lubricants, no liquids, no creams, no gels, no water - should be applied to the skin surface.
- Only use **no!no! Skin** for the purposes described in this user manual and according to the treatment instructions.

KEEP THESE OPERATING INSTRUCTIONS FOR FUTURE REFERENCE.

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Radiancy no!no! Skin Device™ 510(k) Submission

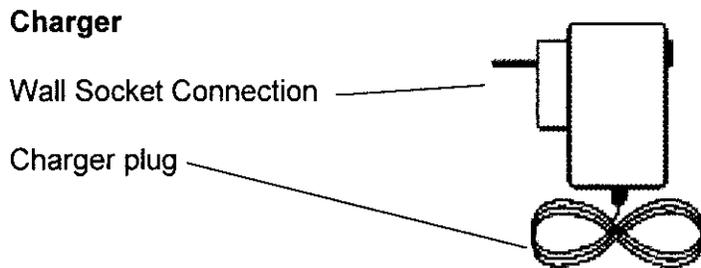
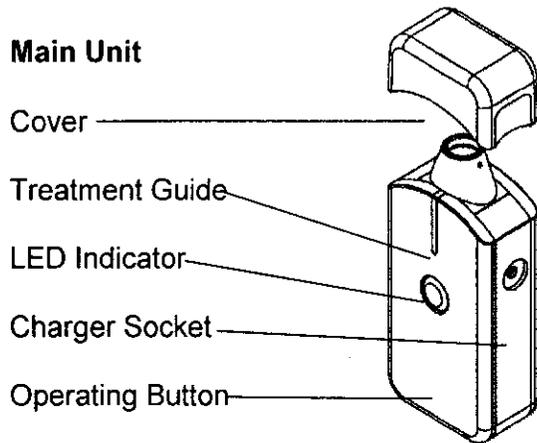
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Meet no!no! Skin

no!no! Skin puts the power and precision of professional acne phototherapy safely into the palm of your hand. no!no! Skin is the quick way to treat individual pimples caused by mild to moderate acne. Simply put the treatment tip over your pimple and push the button.

No warm-up time, no mess and no stress – no!no! Skin helps keep acne under control



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The Pimple Problem

Anatomy of a pimple

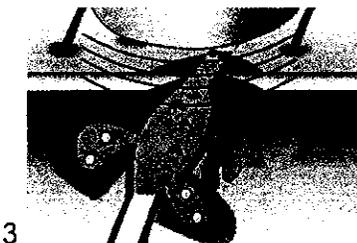
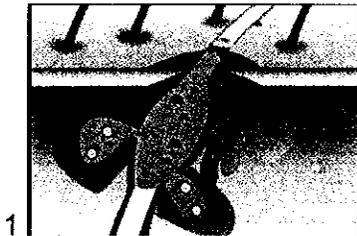
Acne comes in many shapes and sizes. It starts when a build up of oil clogs your pores, trapping dead cells and oil beneath the surface of the skin. This creates an oxygen free environment ideal for the growth of Propionibacterium (P.acnes), the leading cause of acne. (Figure 1)

no!no ! Skin & LHE technology

no!no! Skin is based on LHE technology, used by skin care specialists throughout the world. no!no! Skin combines the healing powers of light and heat to accelerate the healing process of mild to moderate acne sores. Green light, red light and heat reach deep into the pore to stop acne at its source.

Green and red light reach deep into the pore. This begins a process intended to destroy the P.acnes. (Figure 2)

Additional heat speeds up the process. It gently opens the pore, soothes inflammation and reduces swelling. (Figure 3)



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Know Before You no!no! Skin

- Treat yourself in front of a mirror.
- The recommended treatment schedule is two sessions a day, 6-12 hours apart until the pimple heals.
- Treat only one pimple at a time.
- Treat each pimple twice per session.
- Wait 5 seconds before treating the pimple a second time
- One treatment lasts 10 seconds.
- A single beep will sound to signal the start of treatment.
- A double beep will sound to signal the end of treatment.
- A light will flash for the duration of the treatment.
- You may treat as many pimples as you want during each session.

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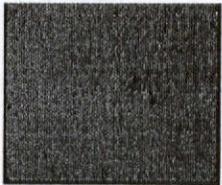
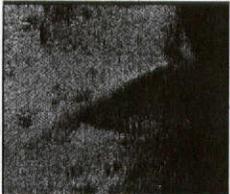
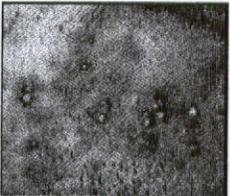
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Acne Level Chart

no!no! Skin is meant for the treatment of individual mild to moderate acne lesions only.

Refer to the chart below to determine if **no!no! Skin** is right for you.

Acne type		Acne definition	Is no!no! skin right for me?
Comedonal acne		Blackheads and whiteheads with slight inflammation (red)	No
Mild acne		Several papules (pimples) with inflammation	Yes
Moderate acne		Many papules & pustules (with pus) with inflammation	Yes
Severe acne		Inflamed papules and pustules with several deep nodular and cystic lesions (hard knots under the skin)	no

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Charging the no!no! Skin

Charge **no!no! Skin** overnight before using it for the first time.

Recharge **no!no! Skin** after each use until the orange light stops blinking and the green light appears.

For safety reasons, your **no!no! Skin** will not operate while plugged into the charger.

Please refer to the table below to understand the different meanings of the LED Indicator located at the bottom of the Treatment Guide.

LED Indicator	Meaning	Course of action
Blinking Orange	Charging	
Steady Green	Fully charged	
3 Long Beeps	Low battery	Need to charge, but can still operate
Steady Orange for 10 seconds	Very low battery	Charge immediately, will not work

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Operating Instructions

no!no! Skin helps speed the healing process of mild to moderate inflammatory acne. A patented treatment tip provides therapeutic light and heat to the body. **no!no! Skin** can be used on the face, arms, back, and chest.

Important Notes:

- Your skin must be clean and completely dry before use.
- **no!no! Skin** must be charged overnight before initial use.
- For safety reasons, **no!no! Skin** will not operate when plugged into the charger.
- Test **no!no! Skin** on your arm before applying it to your face to become familiar with the pulsing sensation.
- Treat only areas that are currently affected by acne.
- Treat each pimple individually.
- Treat each pimple twice before proceeding to the next pimple.
 1. Unplug the charger from the electrical outlet.
 2. Disconnect **no!no! Skin** from the charger.
 3. Remove the cover.
 4. Look in a mirror when treating the face area or any other area that you do not have a direct view of.
 5. Line the Treatment Guide up with the pimple.
The Treatment Guide is located on the front of **no!no! Skin**. Refer to the chapter titled "Meet **no!no! Skin**" to see its exact placement.
 6. Place **no!no! Skin** directly against the pimple and in full contact with your skin.
 7. Press the button. A beep will sound to signal the start of treatment.
 8. Keep **no!no! Skin** in full contact with the pimple for the entire treatment (10 seconds). NOTE: If at any time during the treatment tip feels too hot, remove it and press the button to end the sequence.
 9. Treatment is complete when **no!no! Skin** sounds a double beep.
 10. Wait 5-10 seconds and treat the same pimple again.
 11. After treating one pimple twice, you may continue to treat additional pimples if necessary.

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Cleaning Instructions

In order to prevent infection, thoroughly clean the **no!no! Skin** treatment tip before and after each use, especially if used by more than one person. Dip a clean piece of gauze or cloth into rubbing alcohol and gently wipe the treatment tip. Be sure the treatment tip is completely dry before the next use.

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no!no! Skin™

Troubleshooting

no!no! Skin was designed to give you a trouble-free method to deal with acne. However, from time to time, problems may appear.

What do I do if...

my no!no! Skin does not emit a pulse?

Check the power indicator to make sure your no!no! Skin has been fully charged.

Recharge the unit.

I've charged my no!no! Skin, but the power indicator remains at low and it won't emit a pulse?

Check the charger's power cord and plugs for damage. Try another outlet, the one you were using may not be working properly.

If a problems persists, or one that is not mentioned occurs, contact a no!no! Skin service center

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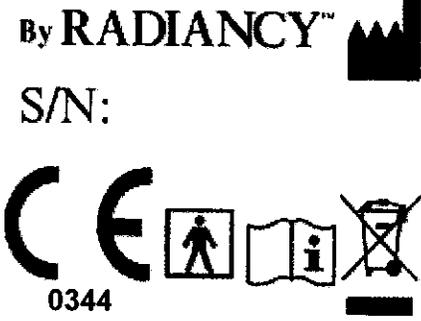
no!no! Skin™

Product Labels

This section describes the labels affixed to the no!no! Skin. It is recommended that users review the meaning of these labels for everyday usage, and in case any details are needed for service.

The table below briefly reviews a number of the internationally recognized symbols that are found on the no!no! Skin main unit and its external package.

This sticker is found on the device.

Label	Location and Comments
	<p>Located at the bottom of the device.</p> <p>This label includes manufacturer details, Standard International Symbols and the system's Lot number.</p>

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no!no! Skin™

Standard International Symbols

Symbol	Meaning
	Degree of protection against electric shock: Type BF applied part
	CE mark presents the compliance to the European Medical Device Directive 93/42/EEC, Class IIa device. The number (0344) is of the certifying body, KEMA Notified Body
	The symbol on the label affixed to this device means "Attention, consult accompanying documents".
	Manufacturer
	Protect the environment by not disposing of this product with household Waste (2002/96/EC). Check your local authority for recycling advice and facilities (Europe only).

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no!no! Skin™

Technical Specifications

Light Source.....Halogen Lamp with Light & Heat Energy (LHE)

Wavelength Range.....480 – 2000 nm

Fluence.....6J/cm²

Pulse Train.....20 pulses per application

Treatment Area.....0.5 cm²

Treatment Time.....10 seconds

Classification..... Internally Powered Equipment, Type BF

Mode of Operation.....Short-time Operation

Operating Conditions.....Ambient Temperature: +5°-35°

Electrical Requirements for Battery Charger.....Electrical Input Voltage 100 – 240VAC
at 50/60Hz.

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no!no! Skin User Manual, Revision 04, July 2008 Part Number: 2018590.

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LHE® is a registered trademark, and Radiancy™ and no!no! are trademarks of Radiancy in the United States and in other countries.

The Quality Management System of Radiancy complies with the Quality Management Standard ISO 13485:2003.



Manufacturer: Radiancy (Israel) Ltd., 9 Gan-Rave St., P.O. Box 13111, Industrial Park, Yavne 81223, Israel, Tel: 972-8-943-3100, Fax: 972-8-943-8020. www.radiancy.com



European Representative: Obelis S.A, Av. de Tervuren 34 Bte .44, B-1040 Brussels, Belgium: Tel: 32 (0) 2 732 5954, Fax: 32 (0) 2 732 6003, GSM 07545 4660, e-mail: obelis@info.be



The CE mark presents the compliance to the European Medical Device Directive 93/42/EEC, Class IIa device. The number (0344) is of the certifying body KEMA Notified Body.

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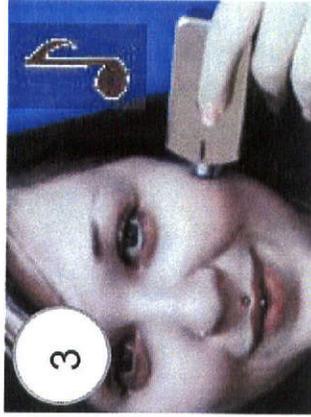
no!no! skin Quick Guide



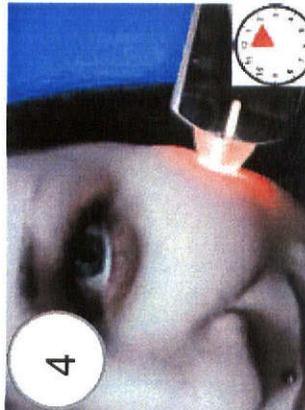
Remove cap.



Place on pimple.



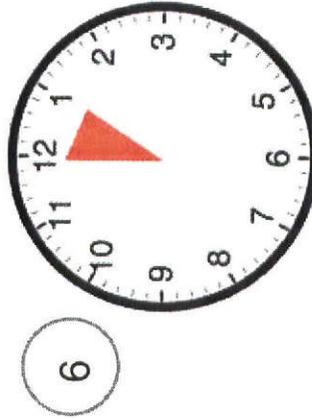
Push button.



Keep on pimple for 10 seconds.



Remove **after** you hear 2 beeps.



Wait 5 seconds and treat the same pimple a second time.

Treat each pimple no more than **twice** a session.

This is only a guide. Read the **ENTIRE** user manual before treating yourself with no!no! skin.

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14. Sterilization and Shelf Life

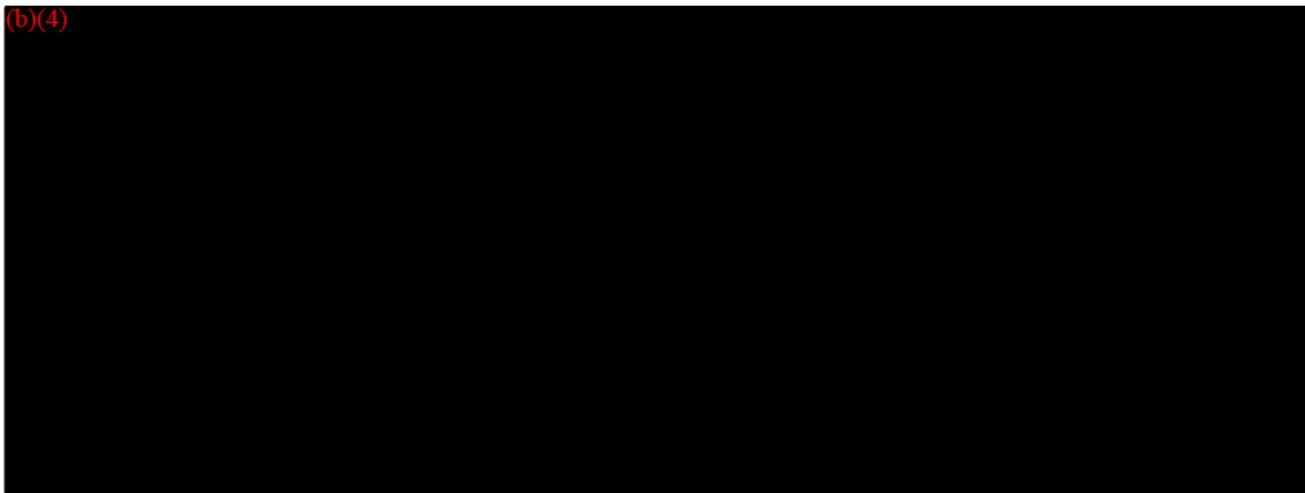
No!no! Skin is not sold sterile or intended to be sterilized by the user. Cleaning instructions are provided in the User Manual in Section 13.

15. Materials Used for the Cover Tip of the no!no! Skin™

The cover tip of the device is placed on the skin, around the acne lesion targeted for treatment. This part is made from Makrolon® 2458 and color 550115.

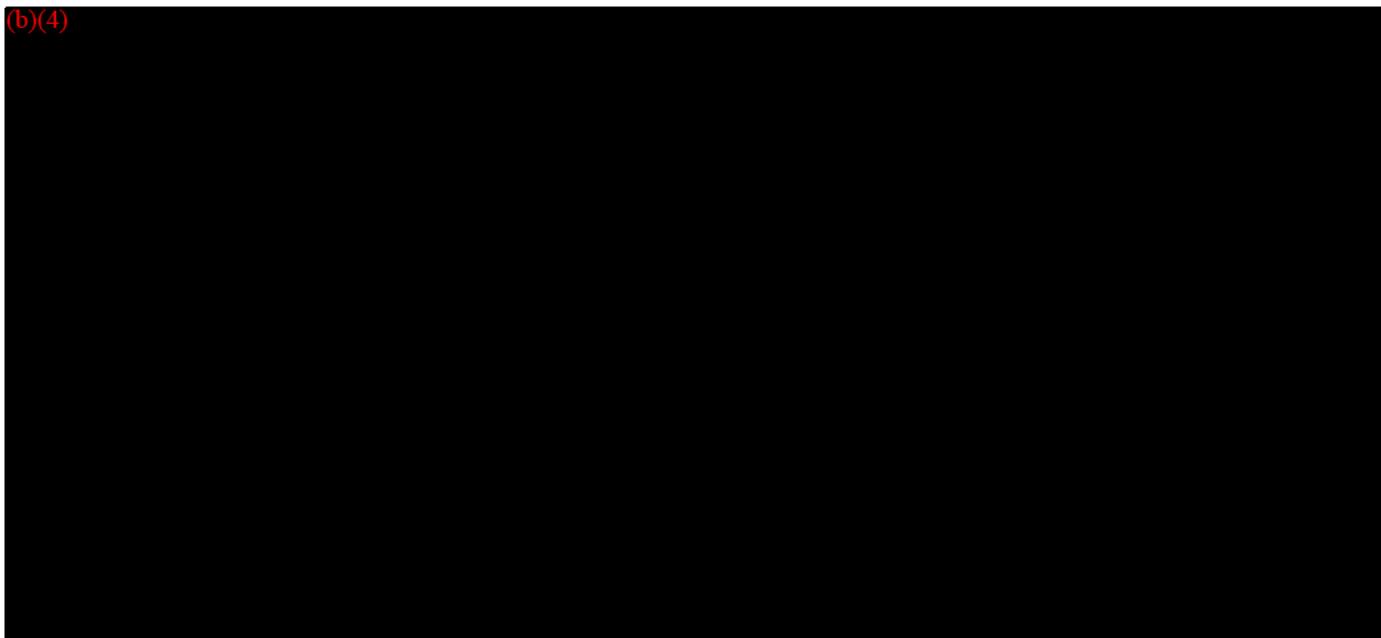
Biocompatibility certificates for this material are included in Appendix 15-A.

(b)(4)

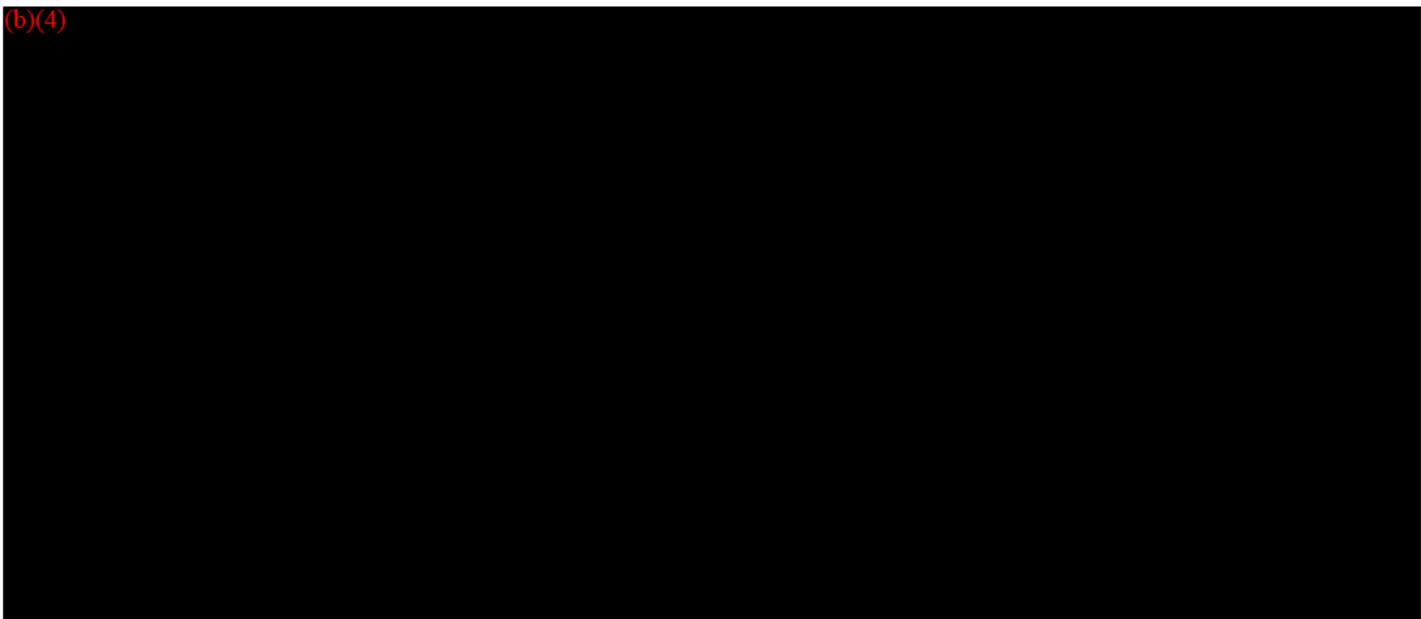


CERTIFICATE OF CONFORMANCE

(b)(4)



(b)(4)



(b)(4) Material specifications





MAKROLON® 2458

Polycarbonate Resin

2458 High-Productivity, FDA-Medical Quality Grade with release

Product Information

Description

Makrolon 2458 polycarbonate resin is a linear, low-viscosity, high-performance thermoplastic produced in pellet form for processing primarily by injection molding. A unique technology enables this polycarbonate to maintain mechanical properties similar to lower-melt-flow grades of polycarbonate, while offering improved flowability for increased design flexibility. Makrolon 2458 contains an internal mold release additive. It is available in natural, clear tints, select transparent, translucent, opaque colors and special effects.

By broadening the processing window, Makrolon 2458 resin is designed to permit faster cycling and higher productivity. Based upon tests conducted at Bayer laboratories, a processing comparison of the high-productivity grade with production runs of standard polycarbonate has demonstrated increases in production rates in excess of 15%. Actual test results may vary, depending on the application and processing conditions. In addition, the increased productivity reduces energy consumption on a unit part basis.

These benefits are the result of low melt viscosity and ease of part ejection. The low viscosity is of particular interest in applications where thin walls exist or the flow length-to-wall thickness is high. Ease of processing at lower temperatures translates to faster cycles, as parts may be produced at lower mold-set-point temperatures and ejected after shorter cooling times. Although applicable to existing tools, new tool design can take advantage of the low melt viscosity of this grade. Thinner runners and distribution systems can be employed to reduce cycle time. Wall sections in the part can be reduced to conserve materials and contribute faster cycling.

Although small parts offer some of the more attractive benefits of increased productivity, this grade is also a candidate for applications involving large injection molded parts. In both large and small part molding, the same processing allowances exist. Lower melt temperatures and easy release permit demolding with less time necessary for stabilizing the part.

Medical Applications

Makrolon 2458 polycarbonate resin has an excellent balance of engineering properties, including outstanding impact strength and ductility, a wide range of service temperatures, excellent electrical properties, and dimensional stability. Makrolon 2458 is used in a variety of applications in the medical market and where multicavity tooling is used.

As with any product, use of Makrolon 2458 resin in a given application must be tested (including but not limited to field testing) in advance by the user to determine suitability.

Biocompatibility: Certain color formulations of Makrolon 2458 polycarbonate resin (such as clear tint 550115) meet the requirements of the FDA-modified ISO 10993, Part I "Biological Evaluation of Medical Devices" tests with human tissue contact time of 30 days or less. Only products that meet these requirements may be considered candidates for applications requiring biocompatibility.

Regrind must not be used in medical applications requiring biocompatibility.

Page 1 of 5 — Document contains important information and must be read in its entirety.

Manufacturer's Responsibility: It is the responsibility of the medical device, biological product or pharmaceutical manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including Makrolon 2458 resin, used in its final product in order to ensure safety and compliance with FDA requirements. This determination must include, as applicable, testing for suitability as an implant device and suitability as to contact with and/or storage of human tissue and liquids including, without limitation, medication, blood or other bodily fluids. Under no circumstances may Makrolon 2458 resin be used in any cosmetic, reconstructive or reproductive implant applications. Nor may Makrolon 2458 resin be used in any other bodily implant applications or any applications involving contact with or storage of human tissue, blood, or other bodily fluids for greater than 30 days, based on FDA- modified ISO 10993, Part 1 "Biological Evaluation of Medical Devices" tests.

The suitability of a Bayer product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

Single-use medical devices made from a Bayer product are not suitable for multiple uses. If the medical device is designed for multiple uses, it is the responsibility of the Manufacturer to determine the appropriate number of permissible uses by evaluating the device under actual sterilization and end-use conditions and to adequately advise and warn purchasers and users thereof.

Sterilization: Parts molded from Makrolon 2458 resin can be sterilized by using radiation, ethylene oxide, or steam autoclaving. When sterilizing with steam, germicides and detergents must be rinsed thoroughly from polycarbonate parts prior to autoclaving. Failure to thoroughly remove germicides and detergents from the part prior to autoclaving may cause accelerated degradation of the polycarbonate.

Steam sterilization temperatures for parts made of Makrolon polycarbonate must not exceed 250° F (121°C) to avoid part deformation. Please note that permanent immersion of polycarbonate parts in water above 140°F (60°C) or in steam causes loss of material properties and must be avoided. Furthermore, condensed steam should not be allowed to accumulate, as this may cause damage to parts. Polycarbonate parts should also be protected from damage by substances such as alkaline corrosion inhibitors, which are frequently added to boiler feed water.

The sterilization method and the number of sterilization cycles a medical device made from Makrolon 2458 resin can withstand will vary depending upon color formulation, part design, processing parameters, sterilization temperature, and chemical environment. Therefore, the Manufacturer must evaluate each device to determine the sterilization method and the number of permissible sterilization cycles appropriate for actual end-use requirements and must adequately advise and warn purchasers and users thereof.

Drying

All polycarbonate resins are hygroscopic and must be thoroughly dried prior to processing. A desiccant dehumidifying hopper dryer is recommended. To achieve a moisture content of less than 0.02%, hopper inlet air temperature should be 250°F (121°C) and inlet air dew point should be -20°F (-29°C) or lower. The hopper capacity should be sufficient to provide a minimum residence time of 4 hours. Additional information on drying procedures is available in the Bayer brochure *General Drying Guide*.

Processing

Makrolon 2458 resin may be easily processed on commercially available molding equipment suitable for injection molding of polycarbonate. Barrel temperatures may be reduced by up to 45°F (25°C) below normal processing conditions for standard polycarbonate due to ease of cavity fill. Lower viscosity also means that lower primary and secondary injection pressures may be used and that molded-in stresses should be lower. A lower melt temperature permits the use of shorter hold and cure times. The shorter molding cycle is complemented by ease of part ejection at high part temperatures.

Typical processing parameters are noted below. Actual processing conditions will depend on machine size, mold design, material residence time, shot size, etc.

Typical Injection Molding Conditions	
Barrel Temperatures:	
Rear	445°-495°F (229°-257°C)
Middle	510°-550°F (266°-288°C)
Front	530°-570°F (277°-299°C)
Nozzle	510°-530°F (266°-277°C)
Melt Temperature	535°-565°F (279°-296°C)
Mold Temperature	150°-220°F (66°-104°C)
Injection Pressure	10,000-20,000 psi
Hold Pressure	50-70% of Injection Pressure
Shot Size	25-75% of Barrel Capacity
Back Pressure	50-100 psi
Screw Speed	50-75 rpm
Injection Speed	Moderate to Fast
Cushion.....	1/8-1/4 in
Clamp	3-5 ton/in ²

Additional information on processing may be obtained by consulting the Bayer publication *Makrolon Polycarbonate — A Processing Guide for Injection Molding* and by contacting a Bayer MaterialScience technical service representative.

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Typical Properties* for Natural Resin	ASTM Test Method (Other)	Makrolon® 2458 Resin	
		U.S. Conventional	SI Metric
General Specific Gravity Density Specific Volume Mold Shrinkage Water Absorption, Immersion at 73°F (23°C): 24 Hours Equilibrium Melt Flow Rate ^a at 300°C/1.2-kg Load	D 792 D 792 D 792 D 955 D 570 D 1238	0.043 lb/in ³ 23.1 in ³ /lb 0.005–0.007 in/in	1.20 1.20 g/cm ³ 0.83 cm ³ /g 0.005–0.007 mm/mm 0.12% 0.30% 20 g/10 min
Optical Transmittance at 0.125-in (3.2-mm) Thickness Haze at 0.125-in (3.2-mm) Thickness Refractive Index	D 1003 D 1003 D 542		88% <0.8% 1.586
Mechanical^b Tensile Stress at Yield Tensile Stress at Break Tensile Elongation at Yield Tensile Elongation at Break Tensile Modulus (1 mm/min) Flexural Stress at 5% Strain Flexural Modulus Compressive Stress at Yield Impact Strength, Notched Izod: 73°F (23°C) 0.125-in (3.2-mm) Thickness Tensile Impact Strength, "S" Specimen: 0.125-in (3.2-mm) Thickness Rockwell Hardness: M Scale R Scale	D 638 D 638 D 638 D 638 D 638 D 790 D 790 D 695 D 256 D 1822 D 785	9,400 lb/in ² 8,700 lb/in ² 350,000 lb/in ² 12,000 lb/in ² 340,000 lb/in ² 11,000 lb/in ² 14 ft-lb/in 250 ft-lb/in ²	65 MPa 60 MPa 6% 115% 2.4 GPa 83 MPa 2.4 GPa 76 MPa 750 J/m 525 kJ/m ² 75 120
Thermal Deflection Temperature, Unannealed: 0.250-in (6.4-mm) Thickness 264-psi (1.82-MPa) Load 66-psi (0.46-MPa) Load Coefficient of Linear Thermal Expansion mm/mm/°C Thermal Conductivity Specific Heat Relative Temperature Index: 0.059-in (1.5-mm) Thickness Electrical Mechanical with Impact Mechanical without Impact Vicat Softening Temperature, 50N; 50K/h	D 648 D 696 C 177 D 2766 (UL746B) D 1525	259°F 273°F 3.34 E-05 in/in/°F 1.39 Btu-in/(h.ft ² .°F) 0.28 Btu/(lb.°F)	126°C 134°C 6.0 E-05 0.20 W/(m.K) 1,172 J/(kg.K) 125°C 115°C 125°C 144°C
Flammability** Oxygen Index UL94 Flame Class: 0.75-mm (0.030-in) Thickness 1.5-mm (0.059-in) Thickness 2.7-mm (0.106-in) Thickness 3.0-mm (0.118-in) Thickness	D 2863 (UL94)		28% V-2 Rating V-2 Rating HB Rating HB Rating
Weatherability UV Light Exposure and Hot Water Immersion Tests Makrolon 2407 and 2458 resins	(UL746C)		f1 rating
Electrical Volume Resistivity (Tinfoil Electrodes) Surface Resistivity Dielectric Strength (Short Time Under Oil at 1-mm [0.04-in] and 73°F [23°C]) Dielectric Constant (Tinfoil Electrodes): 60 Hz 1 MHz Dissipation Factor (Tinfoil Electrodes): 60 Hz 1 MHz Arc Resistance: Stainless Steel Electrodes Tungsten Electrodes	D 257 D 257 D 149 D 150 D 150 D 495	810 V/mil	1.0 E+16 ohm.cm 1.0 E+16 ohm 32 kV/mm 3.0 2.9 0.0008 0.01 11 s 120 s

* These items are provided as general information only. They are approximate values and are not part of the product specifications. Type and quantity of pigments or additives used to obtain opaque colors and special effects can affect material properties.

** Flammability results are based on small-scale laboratory tests for purposes of relative comparison and are not intended to reflect the hazards presented by this or any other material under actual fire conditions.

^a For information on using melt flow as a quality control procedure, see the Bayer publication Makrolon Polycarbonate — A Processing Guide for Injection Molding.

^b Type and quantity of pigment used in opaque colors can affect mechanical properties, especially toughness.

General Characteristics of Polycarbonate

Hydrolytic Stability: Parts molded from polycarbonate absorb only 0.15 to 0.19% water at room temperature and 50% relative humidity. Dimensional stability and mechanical properties remain virtually unaffected. Even with immersion in water, dimensional changes measure only about 0.5%. Although frequent, intermittent contact with hot water does not harm polycarbonate, continuous exposure to humidity or water at high temperatures (>140°F/60°C) is not recommended due to hydrolytic degradation, which reduces impact strength and tensile properties.

Gas Permeability: Steam permeability, measured on 100- μ m thick film, is 15 g/m²·24 h (0.97 g/100 in²·24 h). Significant permeability also exists for other gases, such as hydrogen, carbon dioxide, sulfur dioxide, helium, ethylene oxide, and oxygen.

Chemical Resistance: Polycarbonate is resistant to mineral acids (even in high concentrations), a large number of organic acids, many oxidizing and reducing agents, neutral and acidic saline solutions, some greases and oils, saturated aliphatic and cycloaliphatic hydrocarbons, and most alcohols. It is important to note that polycarbonate is degraded by alkaline solutions, ammonia gas and its solutions, and amines.

Polycarbonate dissolves in a number of organic solvents, such as halogenated hydrocarbons and some aromatic hydrocarbons. Other organic compounds cause polycarbonate to swell or stress-crack,

e.g., acetone and methyl ethyl ketone. Since chemical resistance to various media is dependent on variables, such as concentration, time, temperature, part design, and residual stresses, the above information should serve only as a guideline. It is imperative that production parts be evaluated under actual application conditions prior to commercial use.

Regulatory Compliance Information

Some of the end uses of the products described in this bulletin must comply with applicable regulations, such as FDA, NSF, USDA, and CPSC. If you have any questions on the regulatory status of these products, contact your Bayer Material Science representative or Bayer's Regulatory Affairs Manager in Pittsburgh, PA.

Health and Safety Information

Appropriate literature has been assembled which provides information concerning the health and safety precautions that must be observed when handling Makrolon 2458 polycarbonate resin described in this bulletin. Before working with these products, you must read and become familiar with the available information on their hazards, proper use, and handling. This cannot be overemphasized. Information is available in several forms, e.g., material safety data sheets and product labels. Consult your Bayer Material Science representative or contact Bayer's Product Safety and Regulatory Affairs Department in Pittsburgh, PA.

Note: The information contained in this bulletin is current as of September 2007. Please contact Bayer Material Science to determine whether this publication has been revised.

Bayer Material Science LLC

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V3b

Page 5 of 5 — Document contains important information and must be read in its entirety.



Makrolon 2458

Grades for / Medical devices

Global grade; MVR 19 cm³/10 min; Medical devices; suitable for ETO and steam sterilization at 121 °C; Complies with the requirements of FDA-modified ISO 10993-1 and USP Class VI; Low viscosity; Easy release; Good hydrolysis resistance; Injection molding; Available in transparent and opaque colors

ISO Shortname

ISO 7391-PC,MR,(,)-18-9

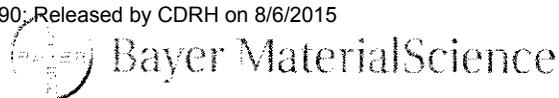
Property	Test Condition	Unit	Standard	Value
Rheological properties				
C Melt volume-flow rate	300 °C; 1.2 kg	cm ³ /(10 min)	ISO 1133	19
C Molding shrinkage, parallel	60x60x2; 500 bar	%	ISO 294-4	0.65
C Molding shrinkage, normal	60x60x2; 500 bar	%	ISO 294-4	0.65
Molding shrinkage, parallel/normal	Value range based on general practical experience	%	acc. ISO 2577	0.5 - 0.7
C Melt mass-flow rate	300 °C; 1.2 kg	g/(10 min)	ISO 1133	20

Mechanical properties (23 °C/50 % r. h.)

C Tensile modulus	1 mm/min	MPa	ISO 527-1,-2	2400
C Yield stress	50 mm/min	MPa	ISO 527-1,-2	65
C Yield strain	50 mm/min	%	ISO 527-1,-2	6.0
C Nominal strain at break	50 mm/min	%	ISO 527-1,-2	> 50
Stress at break	50 mm/min	MPa	ISO 527-1,-2	65
Strain at break	50 mm/min	%	acc. ISO 527-1,-2	120
C Tensile creep modulus	1 h	MPa	ISO 899-1	2200
C Tensile creep modulus	1000 h	MPa	ISO 899-1	1900
Flexural modulus	2 mm/min	MPa	ISO 178	2350
Flexural strength	2 mm/min	MPa	ISO 178	97
Flexural strain at flexural strength	2 mm/min	%	ISO 178	7.1
Flexural stress at 3.5 % strain	2 mm/min	MPa	ISO 178	73
C Charpy impact strength	23 °C	kJ/m ²	ISO 179/1eU	N
C Charpy impact strength	-30 °C	kJ/m ²	ISO 179/1eU	N
Charpy impact strength	-60 °C	kJ/m ²	ISO 179/1eU	N
Charpy notched impact strength	23 °C; 3 mm	kJ/m ²	acc. ISO 179/1eA	65P
Charpy notched impact strength	-30 °C; 3 mm	kJ/m ²	acc. ISO 179/1eA	14C
Izod notched impact strength	23 °C; 3.2 mm	kJ/m ²	acc. ISO 180/A	75P(C)
Izod notched impact strength	-30 °C; 3.2 mm	kJ/m ²	acc. ISO 180/A	12C
C Puncture maximum force	23 °C	N	ISO 6603-2	5100
C Puncture maximum force	-30 °C	N	ISO 6603-2	6000
C Puncture energy	23 °C	J	ISO 6603-2	55
C Puncture energy	-30 °C	J	ISO 6603-2	65
Ball indentation hardness		N/mm ²	ISO 2039-1	115

Thermal properties

C Glass transition temperature	10 °C/min	°C	ISO 11357-1,-2	145
C Temperature of deflection under load	1.80 MPa	°C	ISO 75-1,-2	125
C Temperature of deflection under load	0.45 MPa	°C	ISO 75-1,-2	137
C Vicat softening temperature	50 N; 50 °C/h	°C	ISO 306	145
Vicat softening temperature	50 N; 120 °C/h	°C	ISO 306	146
C Coefficient of linear thermal expansion, parallel	23 to 55 °C	10 ⁻⁶ /K	ISO 11359-1,-2	0.65
C Coefficient of linear thermal expansion, transverse	23 to 55 °C	10 ⁻⁶ /K	ISO 11359-1,-2	0.65
Thermal conductivity	23 °C	W/(m·K)	ISO 8302	0.20
Resistance to heat (ball pressure test)		°C	IEC 60695-10-2	136
Flash ignition temperature		°C	ASTM D1929	480
Self ignition temperature		°C	ASTM D1929	550



Makrolon 2458

Property	Test Condition	Unit	Standard	Value
Other properties (23 °C)				
C Water absorption (Saturation value)	Water at 23 °C	%	ISO 62	0.30
C Water absorption (Equilibrium value)	23 °C; 50 % RH	%	ISO 62	0.12
C Density		kg/m ³	ISO 1183	1200
Bulk density	Pellets	kg/m ³	ISO 60	660
Material specific properties				
Refractive index	Procedure A	-	ISO 489	1.586
Haze for transparent materials	3 mm	%	ISO 14782	< 0.8
Luminous transmittance (clear transparent materials)	1 mm	%	ISO 13468-2	89
C Luminous transmittance (clear transparent materials)	2 mm	%	ISO 13468-2	89
Luminous transmittance (clear transparent materials)	3 mm	%	ISO 13468-2	88
Luminous transmittance (clear transparent materials)	4 mm	%	ISO 13468-2	87
Processing conditions for test specimens				
C Injection molding-Melt temperature		°C	ISO 294	260
C Injection molding-Mold temperature		°C	ISO 294	80
C Injection molding-Injection velocity		mm/s	ISO 294	200

C These property characteristics are taken from the CAMPUS plastics data bank and are based on the international catalogue of basic data for plastics according to ISO 10350.

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Disclaimer for Sales products

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Test values

Unless specified to the contrary, the values given have been established on standardized test specimens at room temperature. The figures should be regarded as guide values only and not as binding minimum values. Please note that, under certain conditions, the properties can be affected to a considerable extent by the design of the mold/die, the processing conditions and coloring.

Medical products

**Only Bayer plastics which fulfil the test requirements of ISO 10 993-1 may be used for medical articles which come within the scope of this standard. However, the biocompatibility tests which we perform according to this standard do not cover the following ranges of application for medical articles manufactured from our material: long-term use over 30 days, particularly use as (cosmetic or reconstructive) implant; long-term contact over 30 days with endogenous substances (blood, tissue, dentin, other body fluids); multiple use for medical applications. Therefore Bayer plastics should not be used for long-term applications or with long-term contact. Use of recycled materials or the use of other additional material components in the finished product. Our test results for biocompatibility do not apply to the use of recycled materials or the use of other additional material components in the finished product. Responsibility of the manufacturer of the medical article: The use of our material outside the above-mentioned test scope of ISO 10 993-1 occurs exclusively on the responsibility of the processor of our material and the manufacturer of the finished product. As regards the production conditions of the processor of our material which are not known to us, it is the responsibility of the processor to ascertain the suitability of our materials in the finished product in terms of directives and statutes to be observed. The suitability of our materials also depends on the ambient conditions (see below) for the finished product. Chemical compatibility, temperature, design of the medical article, method of sterilization, internal stress within the finished article, and external stress all influence suitability, and are therefore the responsibility of the processor and the manufacturer of the finished product. Multiple-use of medical articles: Medical articles which are intended for single use and which were manufactured from Bayer plastic are not suitable for multiple use. If the medical article was manufactured for multiple use, it is the responsibility of the manufacturer of the finished product to determine an appropriate number of times it may be used, by determining and evaluating the conditions of sterilization and final use. Appropriate warnings and instructions must be given to the end user. Sterilization: The use of various methods of sterilization and the permitted number of sterilization cycles for a medical article which is made from our materials depend on the design of the parts, the processing parameters, the sterilization temperature and the chemical environment. Therefore the manufacturer must determine and evaluate the most suitable method of sterilization (and if applicable the permitted number of sterilization cycles) for each medical article. Appropriate instructions and warnings must be given to the end user.

Processing note

Under the recommended processing conditions small quantities of decomposition product may be given off during processing. To preclude any risk to the health and well-being of the machine operatives, tolerance limits for the work environment must be ensured by the provision of efficient exhaust ventilation and fresh air at the workplace in accordance with the Safety Data Sheet. In order to prevent the partial decomposition of the polymer and the generation of volatile decomposition products, the prescribed processing temperatures should not be substantially exceeded.

Information Impact properties

Impact properties: N = non-break, P = partial break, C = complete break

Publisher: Business Development Plastics

Bayer MaterialScience AG,

D-51368 Leverkusen,

www.bayermaterialscience.com

16. Software Documents

The software documents in this section include the following:

1. Software Requirements Specifications (Appendix 16-A) – provides a comprehensive account of the software functions in the device and the interaction with the user.
2. Software Safety Analysis (Appendix 16-B) – provides an analysis of the software hazards in the device and the measures taken to minimize or mitigate those risks. The document includes the following components:
 - a. Software description
 - b. Software level of concern, including a discussion of the process used to characterize the device's level of concern as 'Minor'.
 - c. Verification, validation and testing
3. Software verification test report (Appendix 16-C) – summarizes the software verification tests.

RADIANCY®

DESIGN DOCUMENT

**Software Requirements Specification (SRS) for
no!no!-Skin™**

(b)(4) Material specifications



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1. Introduction

1.1. Purpose

This document describes the Software Requirements Specification (SRS) for the no!no!-Skin Firmware. This document is intended for the R&D group, software developers and testers.

1.2. Scope

This document specifies the requirements for the software of the ST7LITE15B processor.

1.3. Definitions, Acronyms and Abbreviations

The IEEE Standard Glossary of Software Engineering Terminology and the list of terms, acronyms and abbreviations with their associated meanings shown below are used in this document.

T.B.D	To Be Defined
PWM	Pulse Width Modulation

1.4. References

Requirements for the Mechanical and Electrical Characteristics of the no!no!-Skin™ manufactured by Radiancy 701A0011

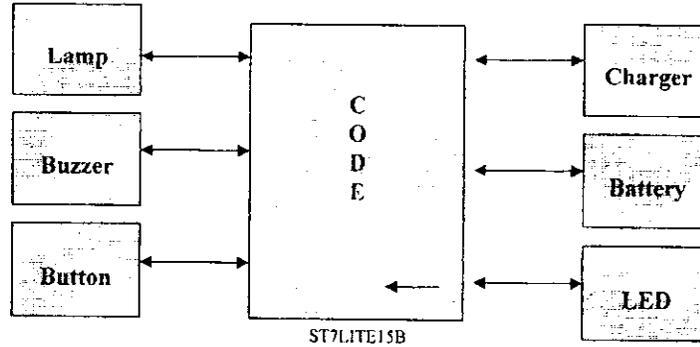
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2. Overall Description

2.1. Product Perspective

The no!no!-Skin™ firmware resides in the controllers Flash memory, and issued on every reset or chip power up.

NO!NO!-Skin High Level Design



2.1.1. Hardware Interfaces

The following are the various characteristics for the hardware interfaces:

PIN	Function	Characteristic
1	+ Voltage	Voltage Supply
2	- Voltage	Voltage Supply
3	Reset	
4	Not in Use	
5	Battery Voltage monitor	Analog Input
6	Charger Inhibit	Analog Input
7	ON Pushbutton	Analog Input
8	Controller Activate	Analog Input
9	Lamp Output B	Digital Output
10	Not in Use	
11	Orange LED	Digital Output
12	Buzzer PWM	Digital Output
13	Charge Enable	Digital Output
14	Lamp Output A	Digital Output
15	Green LED	Digital Output
16	Not in Use	

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2.1.2. Software Interfaces

The following are the software interfaces supported:

- PWM - This interface will be used to drive the halogen lamp according to the specifications.
- Buzzer interface - Different frequencies mechanism for various sounds.

2.1.3. Communication Interfaces

No communication interfaces.

2.1.4. Memory Constraints

The memory constraints defined for this system are shown in the following table:

Memory	Size
ST7LITE15B On chip Flash	4K
On chip SRAM	256 Bytes

2.1.5. no!no!-Skin™ - Operations

The following are the operations required by the system:

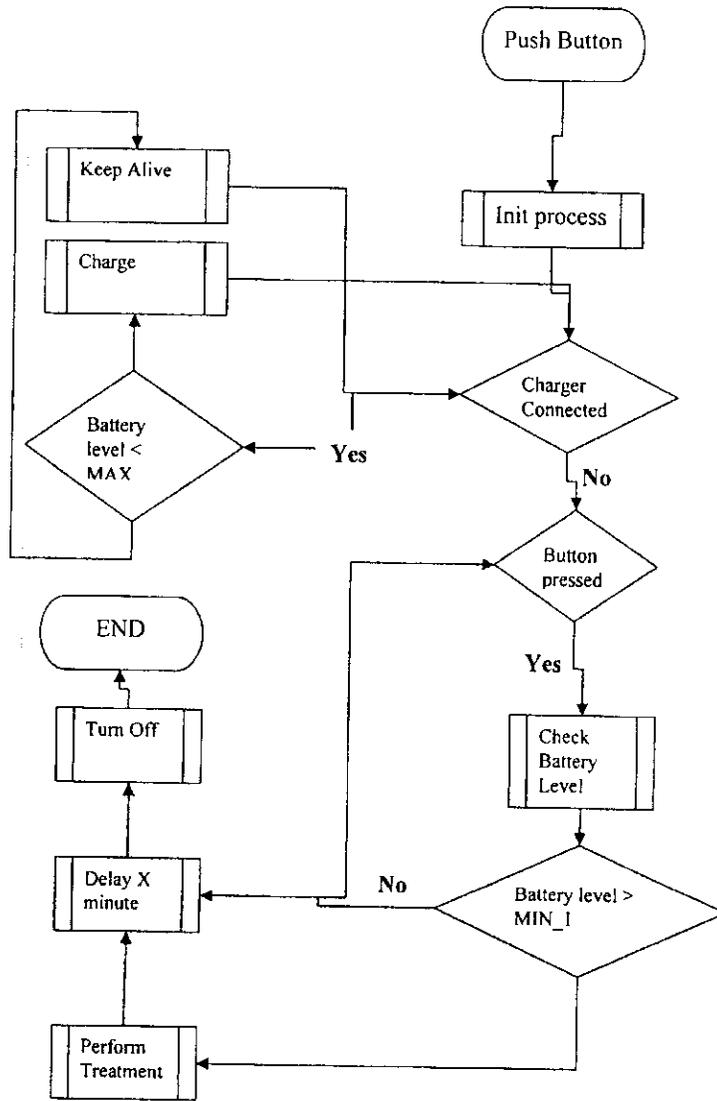
- Check battery level
- Control the lamp
- Charge the battery

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2.2. Product Functions

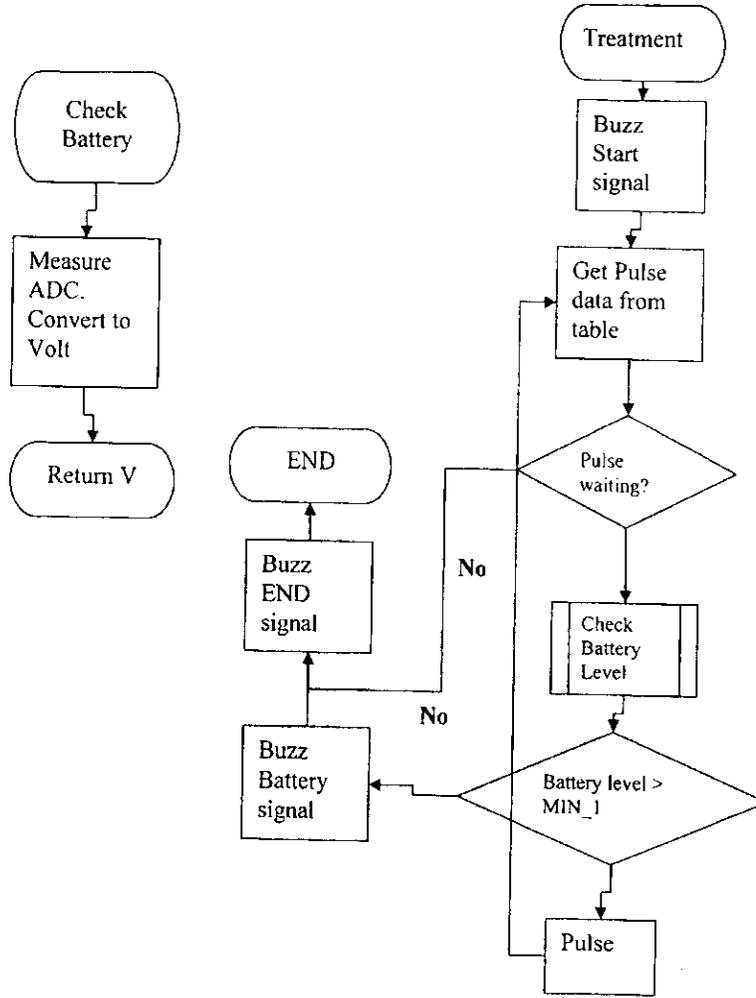
Upon start of code(i.e. after chip reset) the no!no!-Skin™ firmware enters a 'Wait Period' of 0.5 seconds, in this period, the firmware only checks the battery level.

dsPIC Loader Work Flow



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Treatment and Check Battery Work Flow



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After the 'Wait Period' the firmware turns on the PWM for the lamp according to predefined settings.

- Pressing once will turn system ON. Then, wait for 0.5 seconds and start treatment. System will be automatically turned OFF after Y seconds.
- When connecting the charger the firmware switches to a 'Charge Mode', where only the battery meter is active. No treatment is enabled while in 'Charge Mode'.

2.3. Treatment Algorithm:

- When entering treatment state the software will check battery level before each pulse in order to keep the battery level at its limits. Treatment table will be made holding the following:

Pulse number	On Time (ms)	Off Time (ms)
1		
2		
3		
Last Pulse	0	0

- It will be possible to program up to 25 pulses
- The On Time and the Off Time can be individually programmed for each pulse.
- The maximum On Time and Off Time is 2.5 seconds
- The time increments will be 10milli-seconds
- A reading of 0,0 indicates an empty treatment and exit function.
- The table will be defined in an Hfile and will allow the Development Engineer to calibrate the no!no!-Skin™ Treatment Fluence.

2.4. Constraints

The process that drives the halogen lamp will be flexible as much as possible. This means that it will have the ability to change both frequency and duty cycle in run time. This mechanism will be used in order to reach working temperature at minimum time and still keep from over heating.

2.5. Assumptions and Requirements

- One button operation.
- Battery Charging – need to monitor charger state and automatic changeover to trickle mode.

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3. Specific Requirements

This section contains the requirements for this system.

3.1. Hardware Indications

Input/Output pins may be used as inputs to the controller, to eventually allow a single firmware version for several boards.

LED lights are connected to the Input/Output pins as follows:

- One green light –Logic high, turns ON.
- One orange light –Logic high, turns ON.

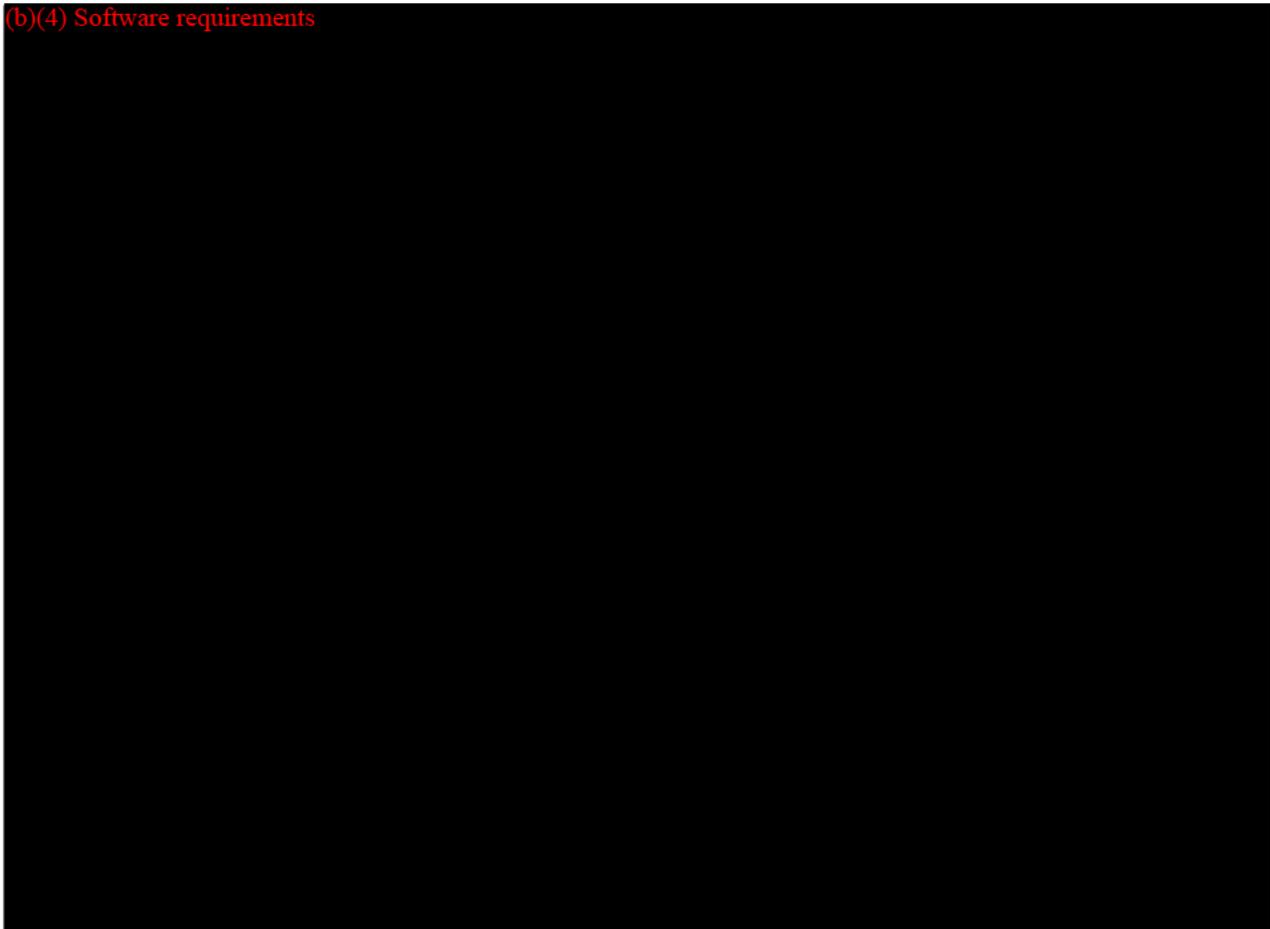
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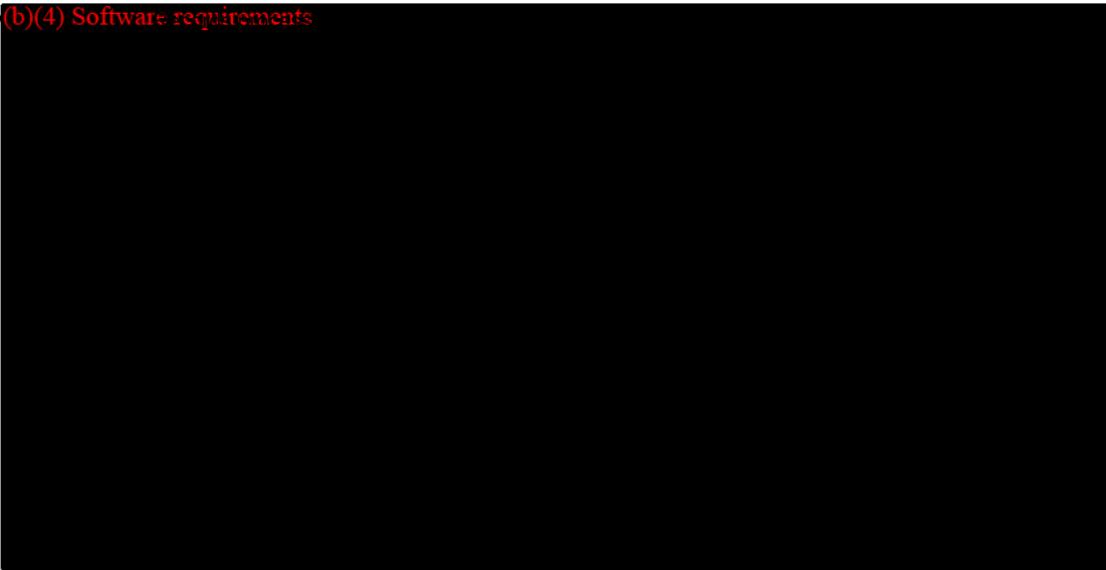
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DESIGN DOCUMENT

Software Safety Analysis for

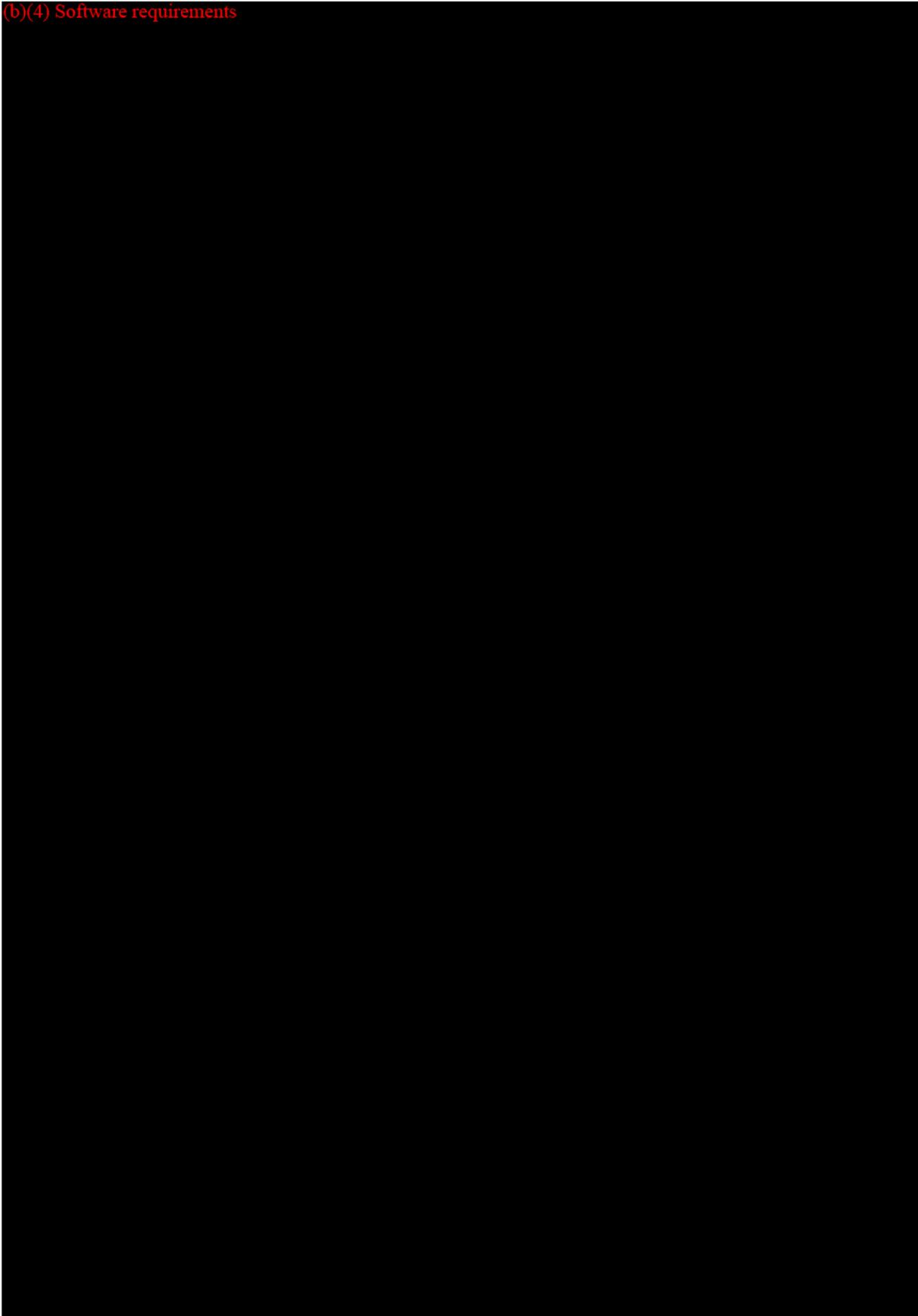
no!no!-Skin™





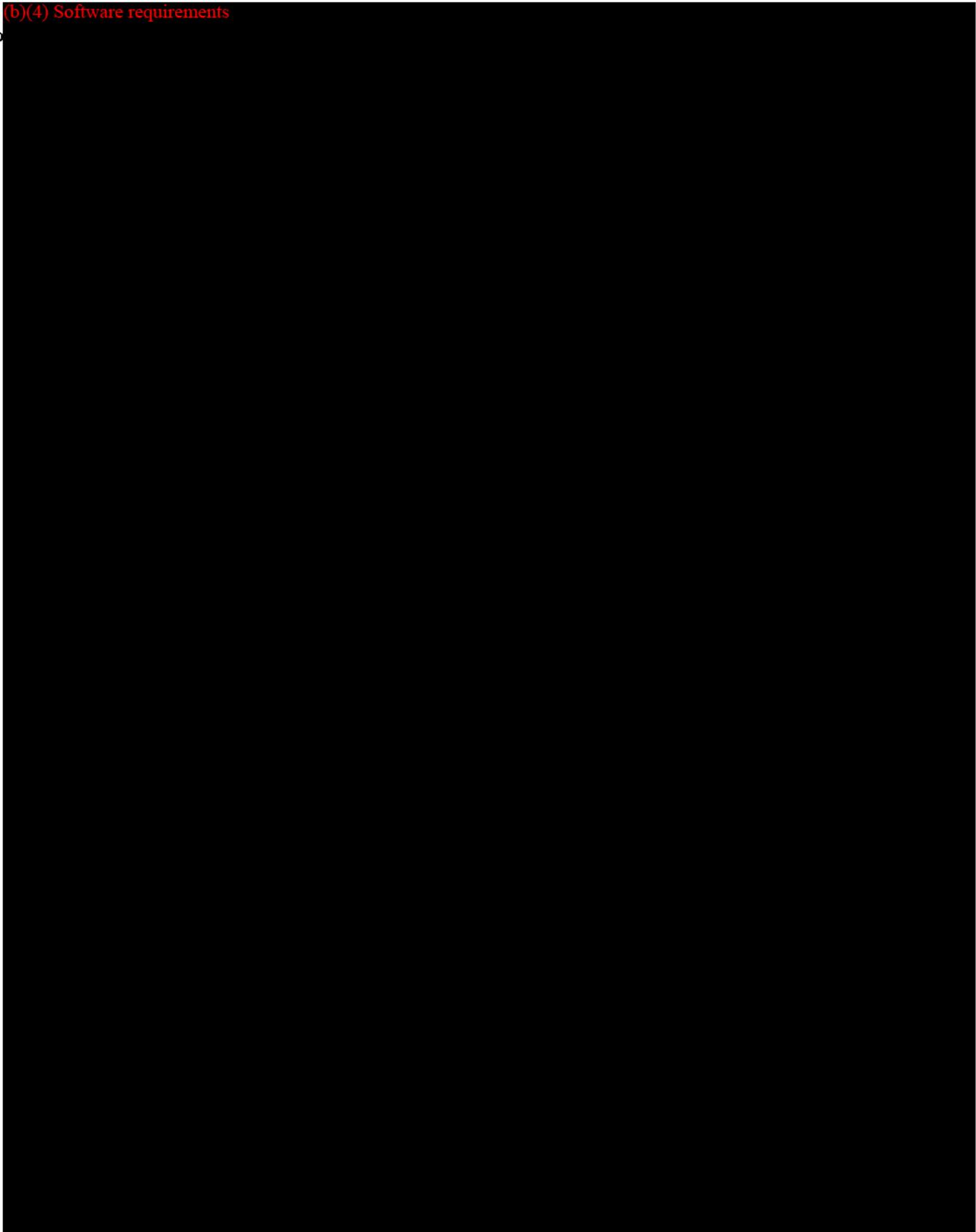
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(b)(4) Software requirements

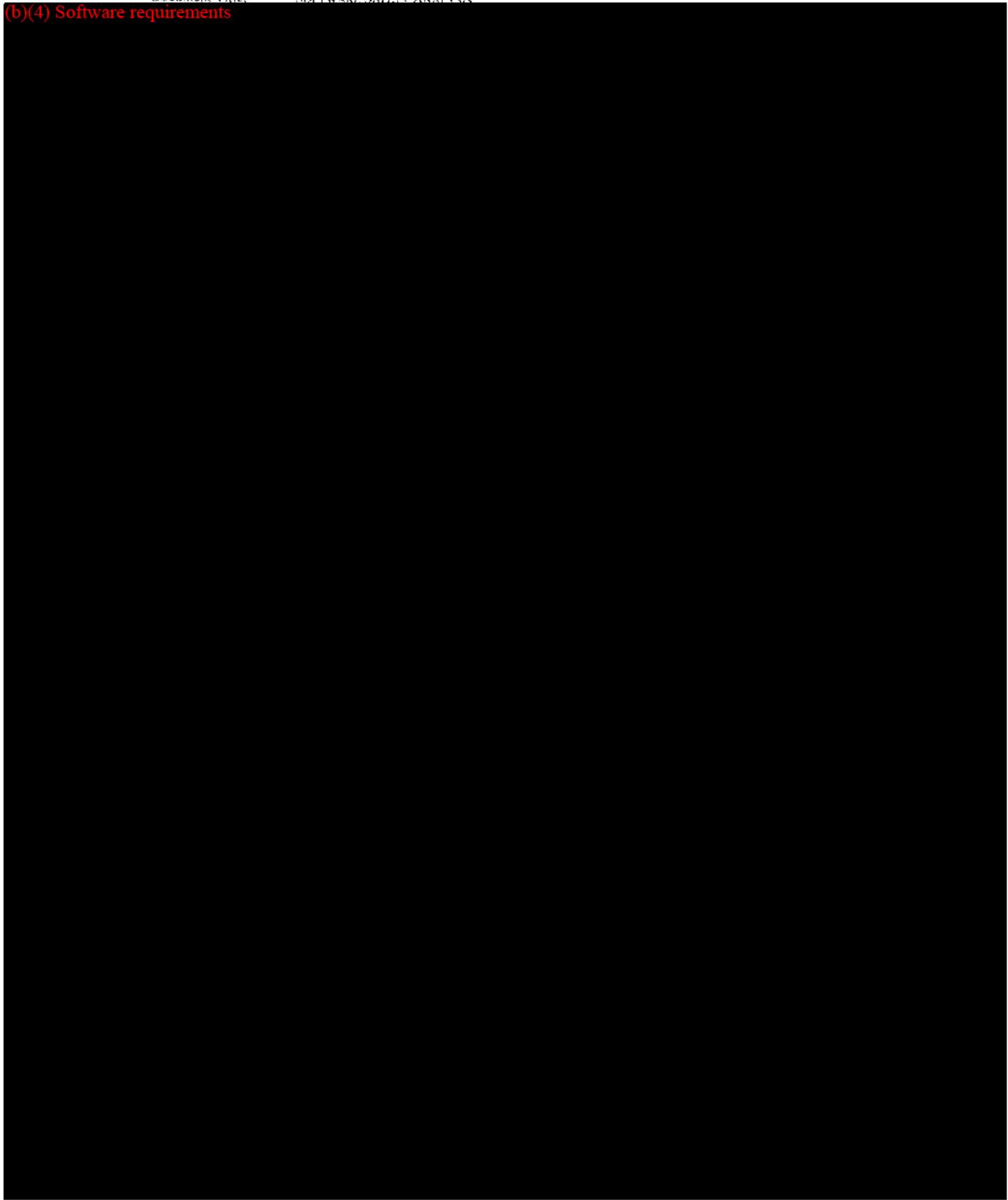


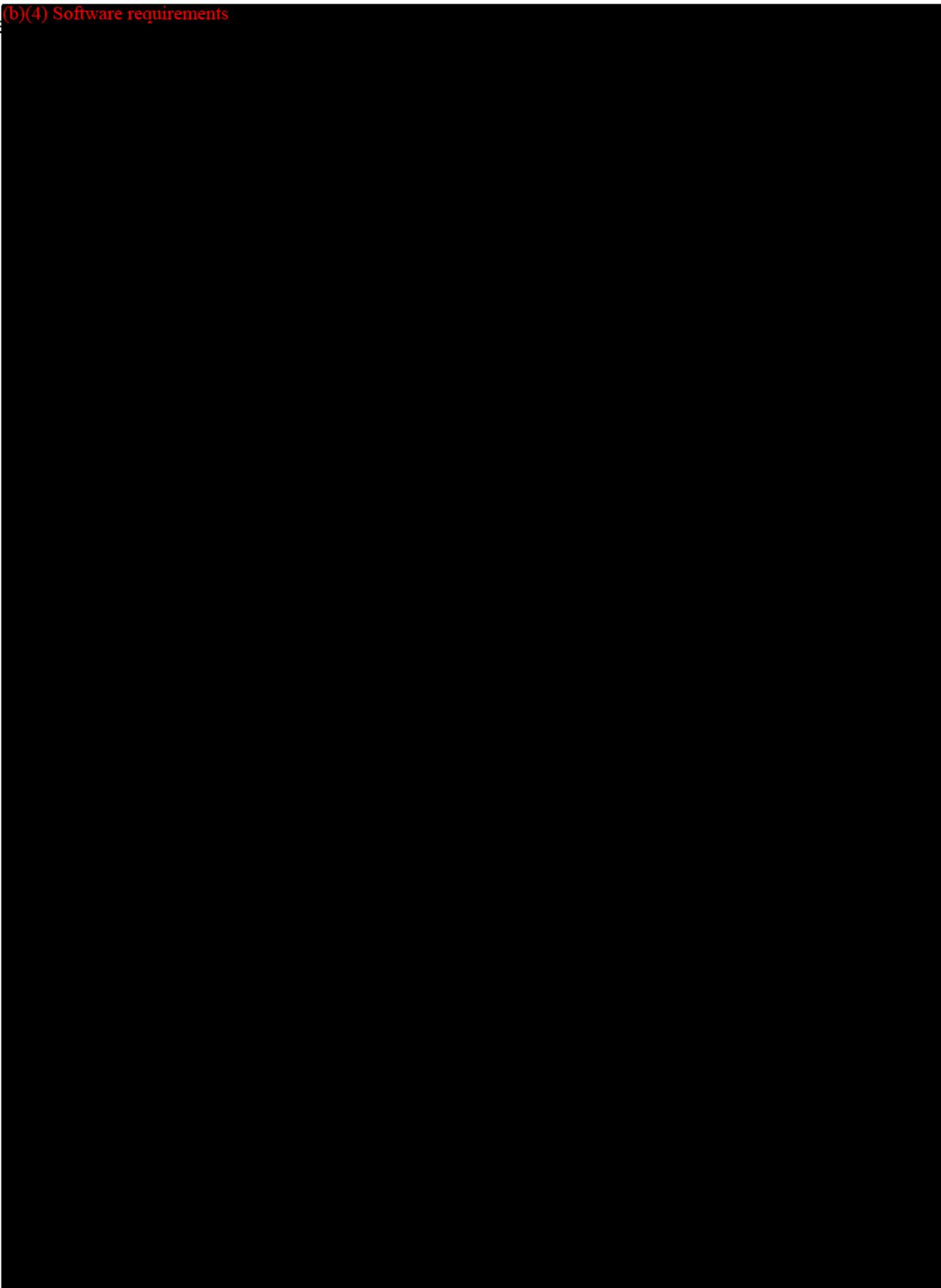
(b)(4) Software requirements

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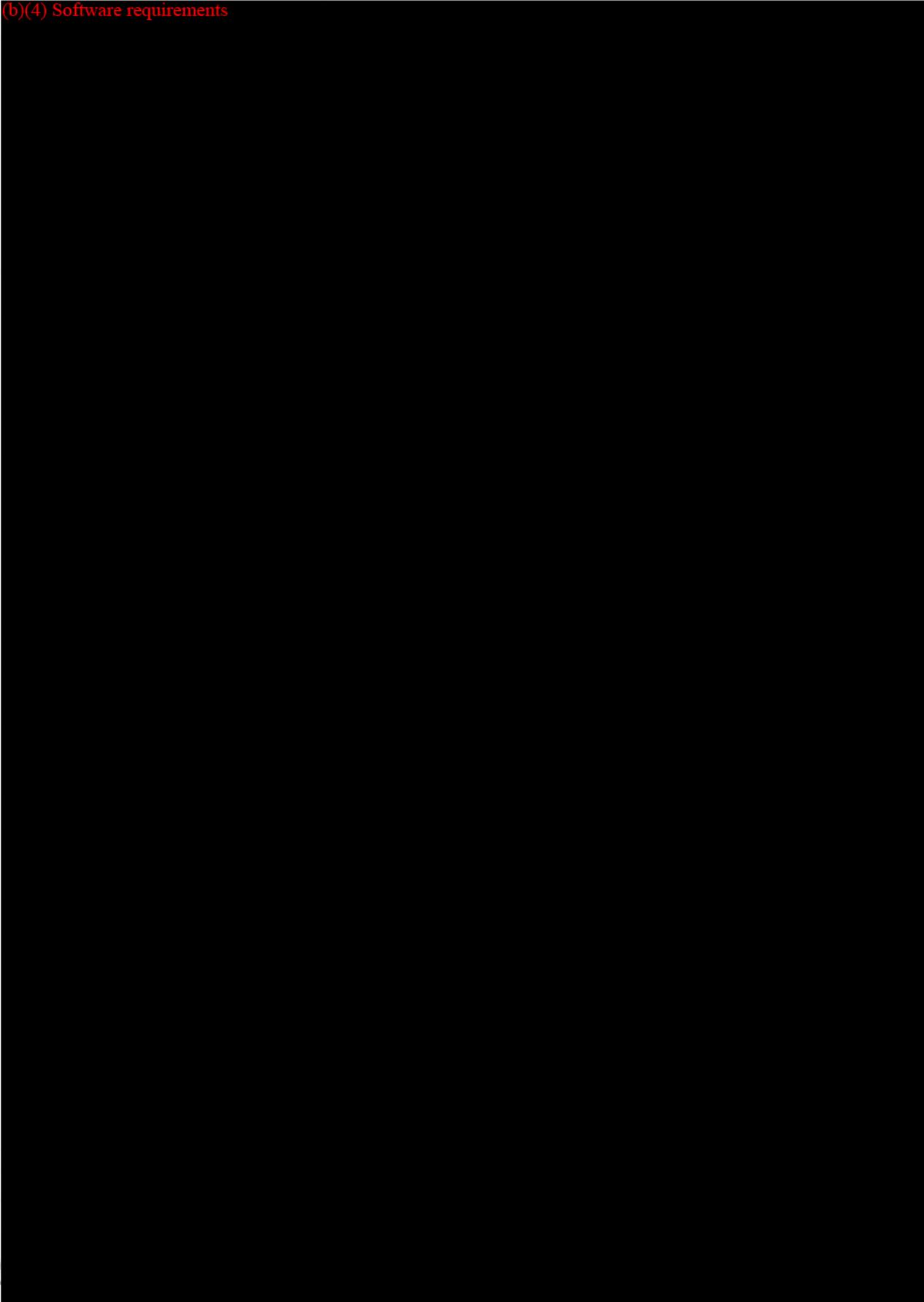
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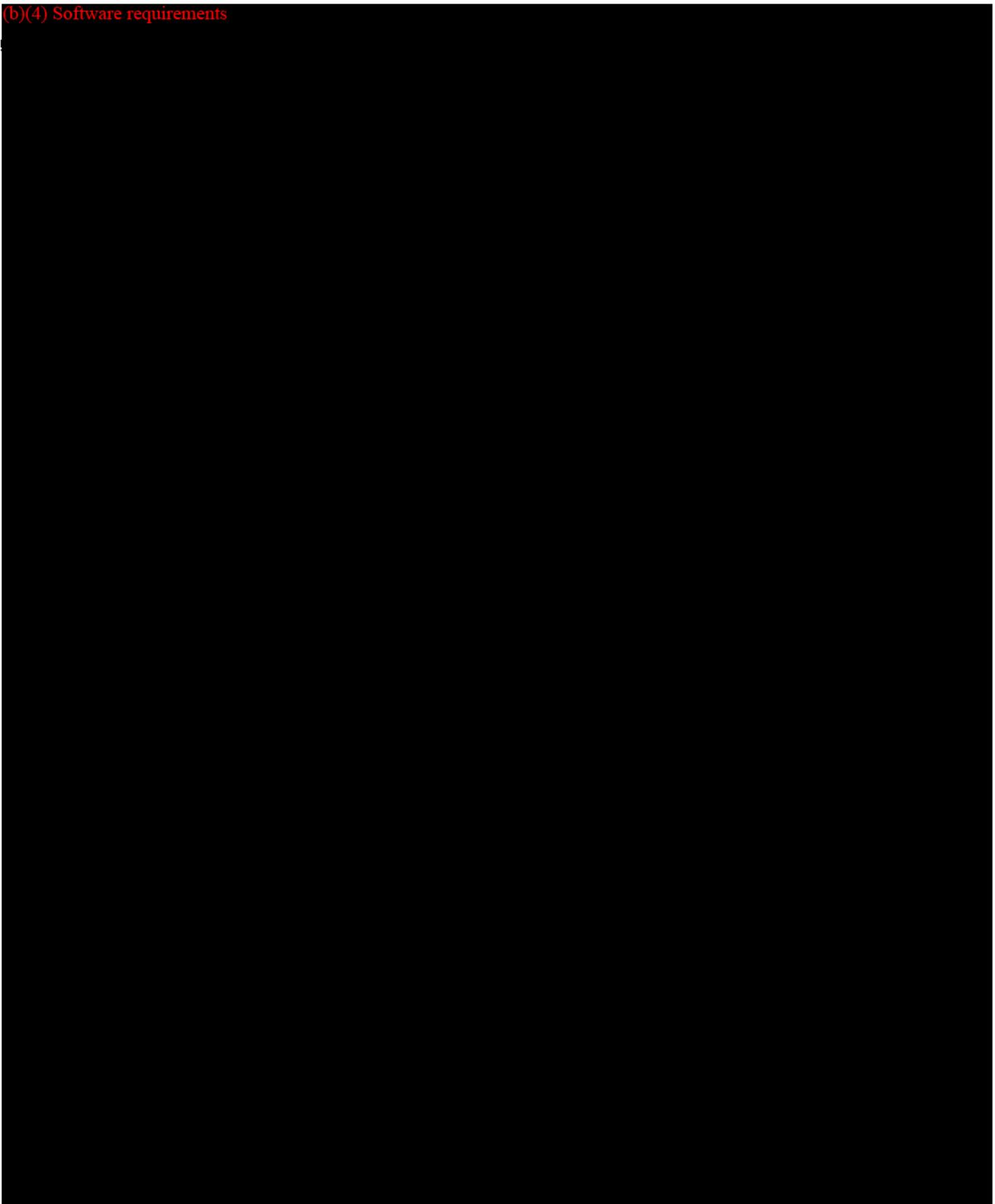


NO!NO!-Skin™
Software Verification tests report form

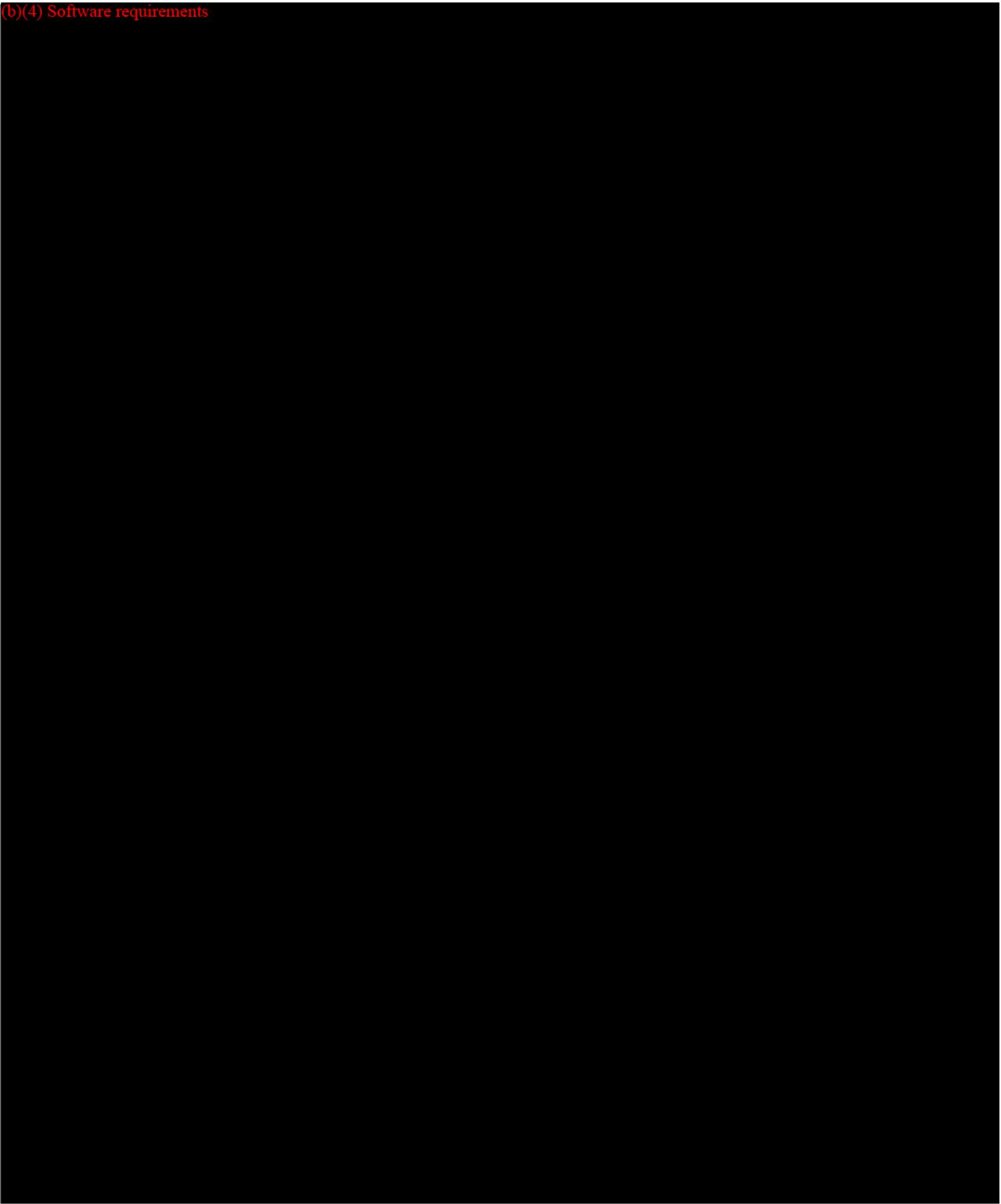
(b)(4) Software requirements



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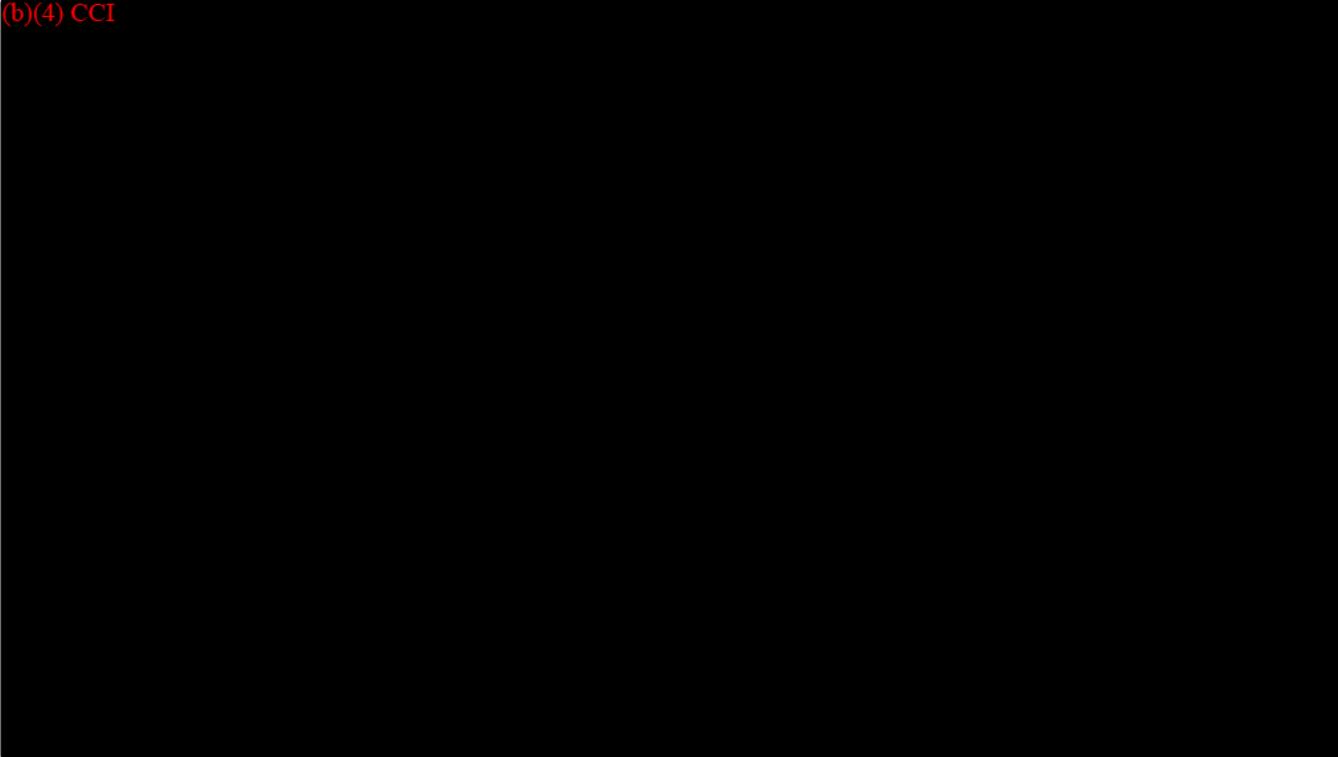


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no!no! Skin™

17. Electromagnetic Compatibility Summary

(b)(4) CCI

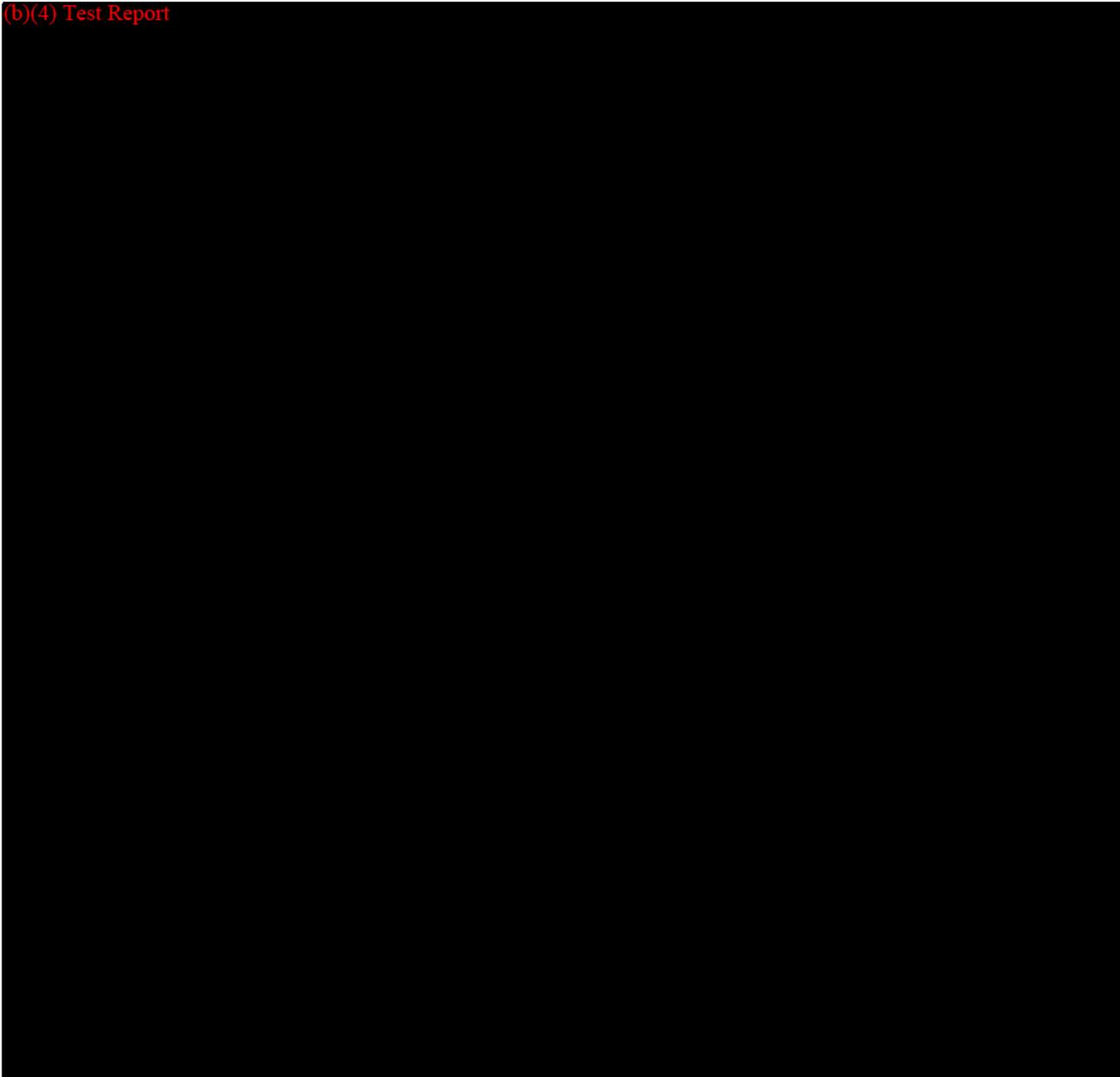


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Radiancy no!no! Skin Device™ 510(k) Submission
Section 17 – Electromagnetic Compatibility

Page 1 of 1

10 29

(b)(4) Test Report



TRF No.: I601-1_C
ITL052I V6.0 21.11.07

TRF originator: UL

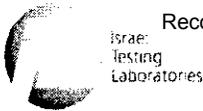
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259



1.2 Abbreviations and Symbols

The following abbreviations and symbols are applicable to this test report:

A/m	ampere per meter
AC	alternating current
AM	amplitude modulation
ARA	Antenna Research Associates
Aux	auxiliary
Avg	average
CDN	coupling-decoupling network
cm	centimeter
dB	decibel
dBm	decibel referred to one milliwatt
db μ V	decibel referred to one microvolt
db μ V/m	decibel referred to one microvolt per meter
DC	direct current
EFT/B	electrical fast transient/burst
EMC	electromagnetic compatibility
ESD	electrostatic discharge
E.U.T.	equipment under test
GHz	gigahertz
HP	Hewlett Packard
Hz	Hertz
kHz	kilohertz
kV	kilovolt
LED	light emitting diode
LISN	line impedance stabilization network
m	meter
mHn	millihenry
MHz	megahertz
msec	millisecond
N/A	not applicable
per	period
QP	quasi-peak
PC	personal computer
RF	radio frequency
RE	radiated emission
sec	second
V	volt
V/m	volt per meter
VRMS	volts root mean square



1.3 List of Accreditations

The EMC laboratory of I.T.L. is accredited by the following bodies:

1. The American Association for Laboratory Accreditation (A2LA) (U.S.A.), Certificate No. 1152.01.
2. The Federal Communications Commission (FCC) (U.S.A.), Registration No. 861911.
3. The Israel Ministry of the Environment (Israel), Registration No. 1104/01.
4. The Voluntary Control Council for Interference by Information Technology Equipment (VCCI) (Japan), Registration Numbers: C-1350, R-1285.
5. Industry Canada (Canada), File No. IC 4025.
6. TUV Product Services, England, ASLLAS No. 97201.
7. Nemko (Norway), Authorization No. ELA 207.

I.T.L. Product Testing Ltd. is accredited by the American association for Laboratory Accreditation (A2LA) and the results shown in this test report have been determined in accordance with I.T.L.'s terms of accreditation unless stated otherwise in the report.



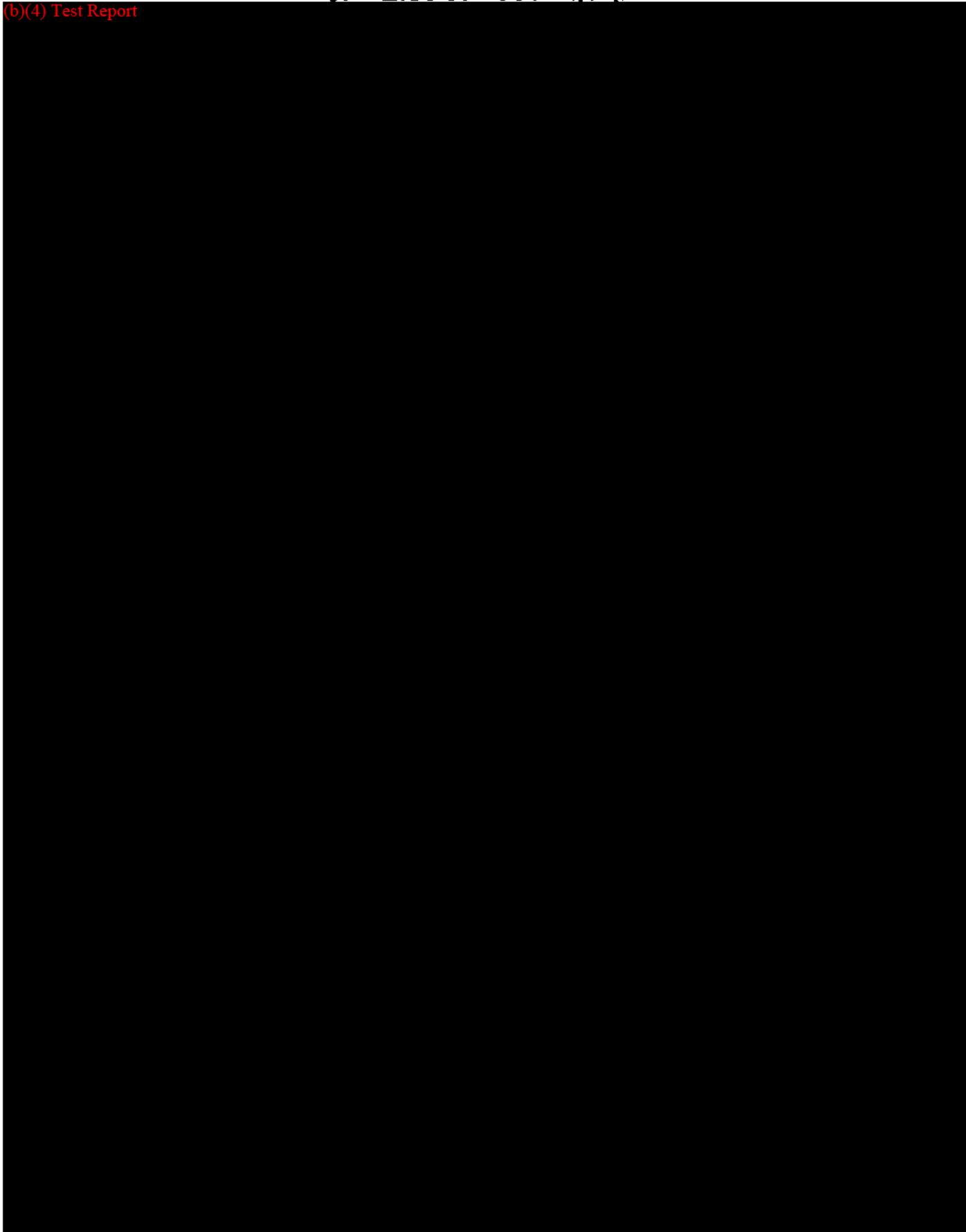
5. Equipment Under Test (E.U.T.) Description

To be described by the manufacturer.



6. List of Test Equipment

(b)(4) Test Report

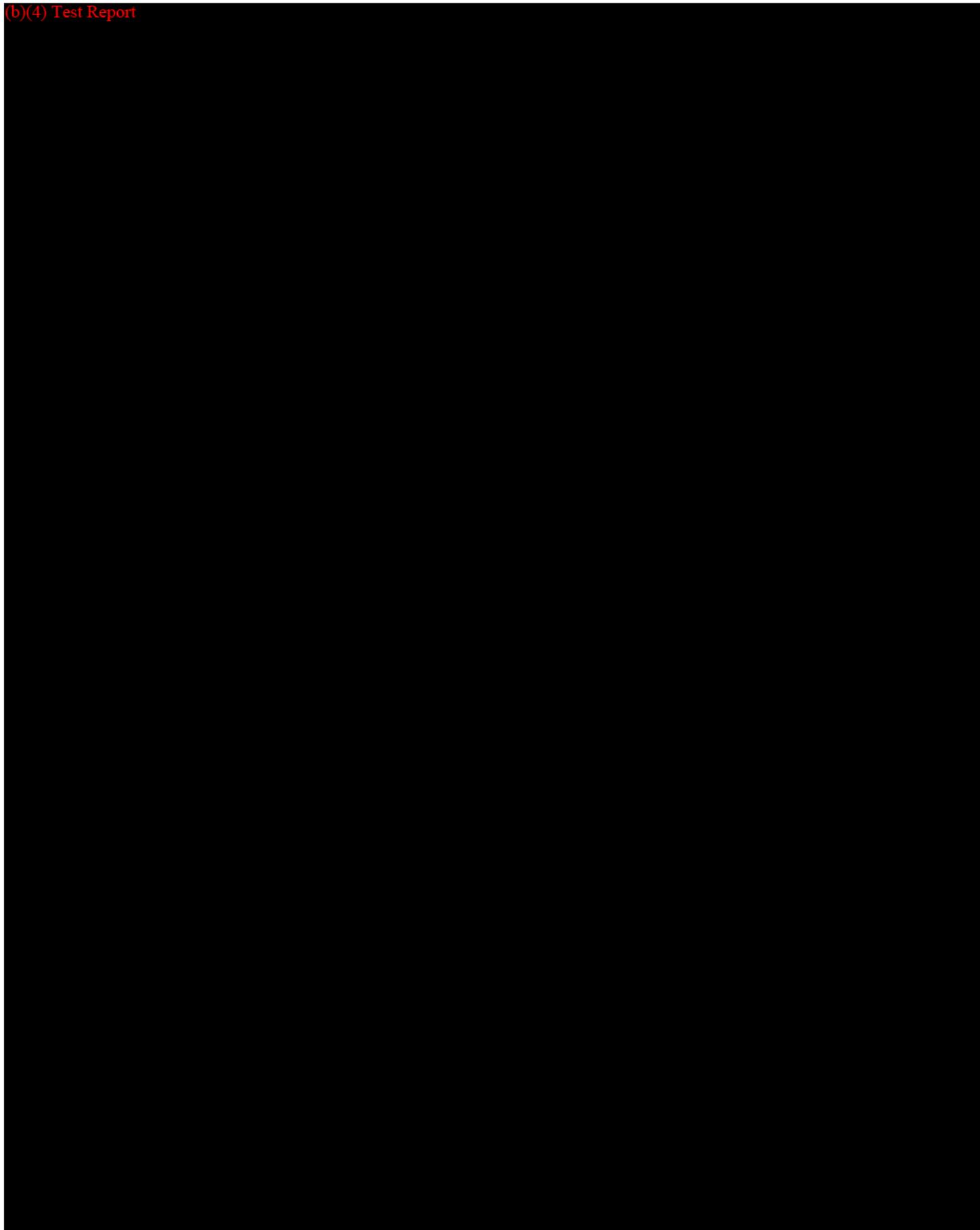


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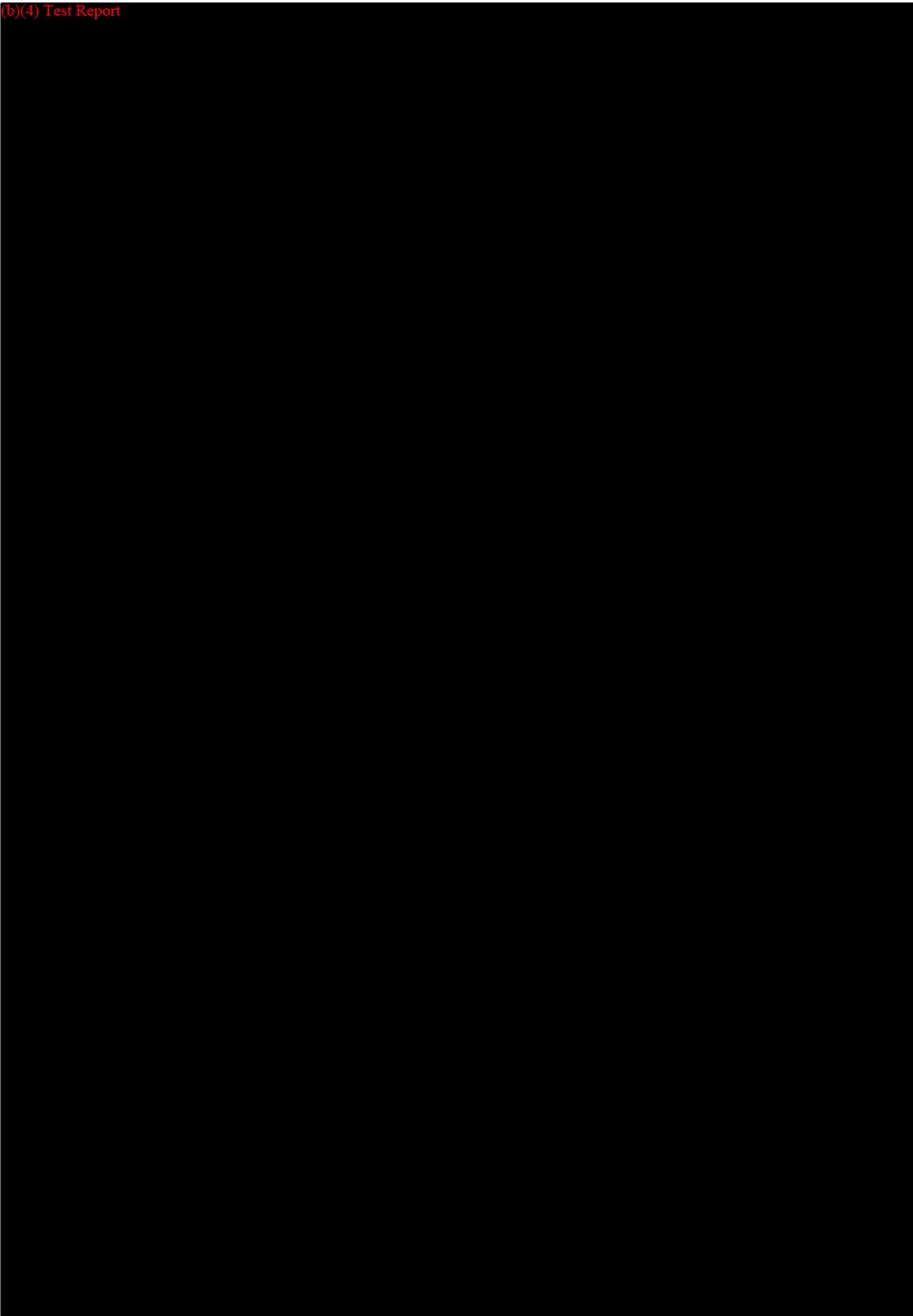


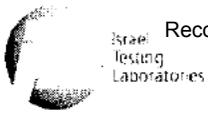
7. E.U.T. Performance Verification

(b)(4) Test Report



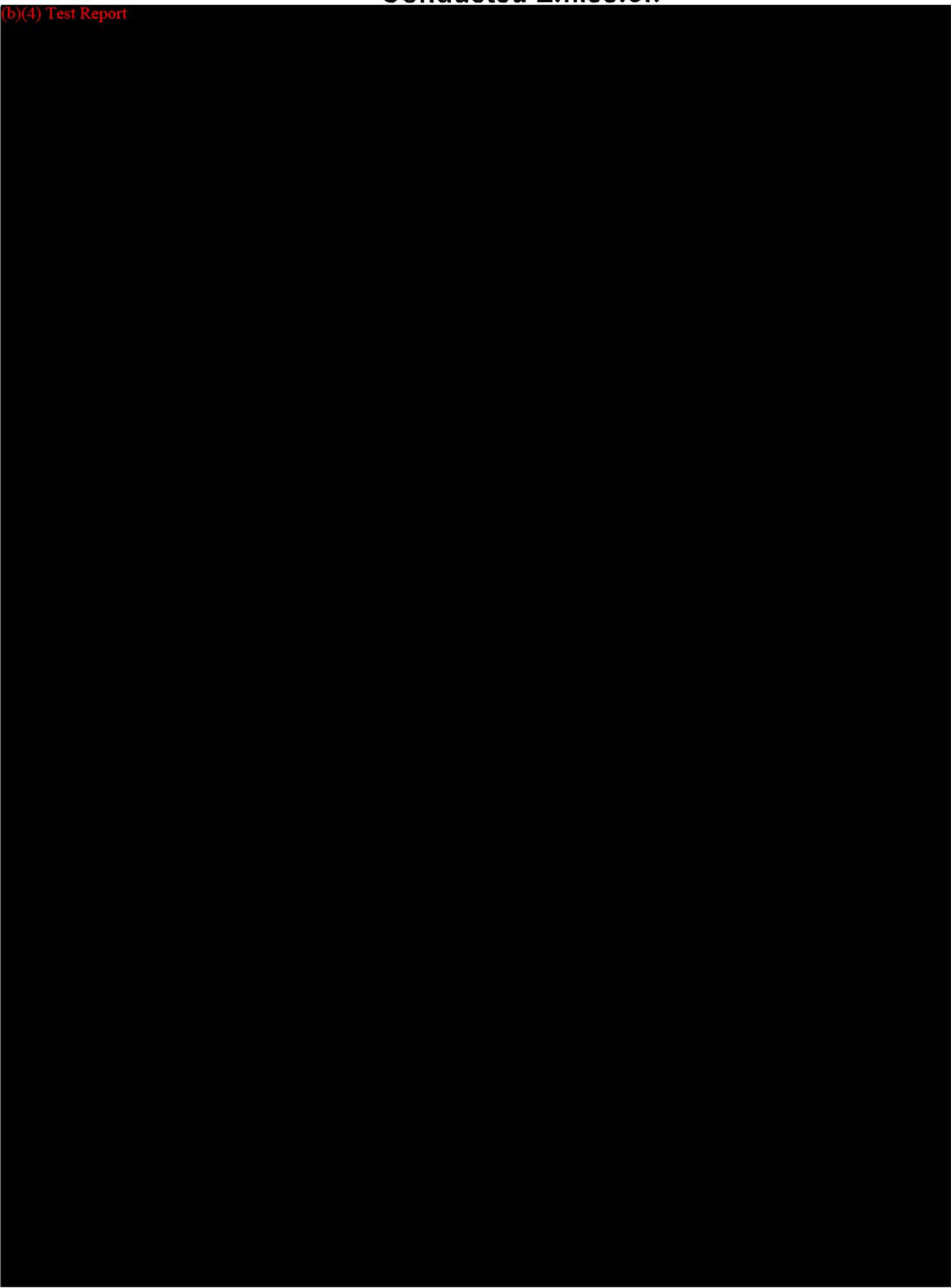
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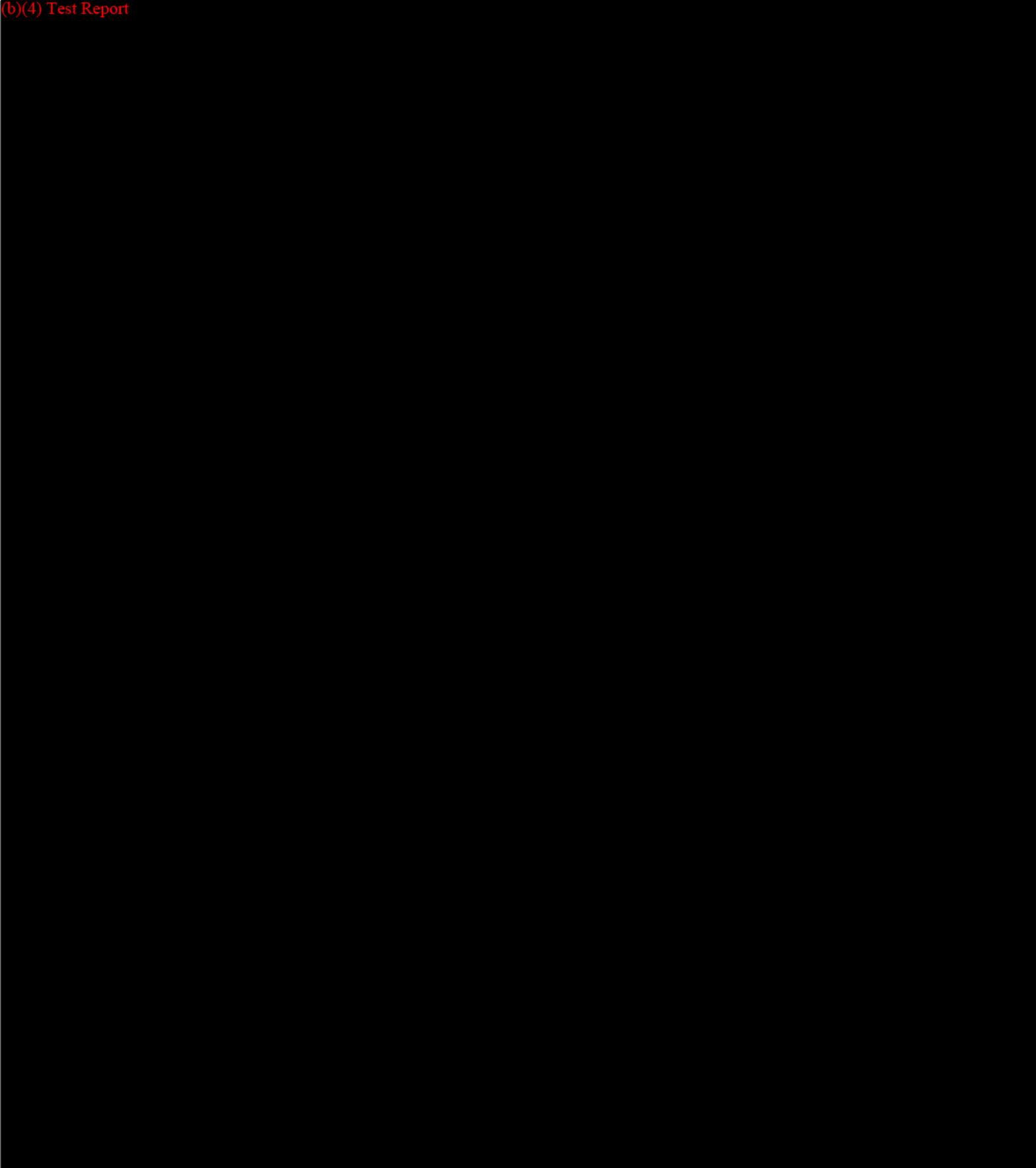


Conducted Emission

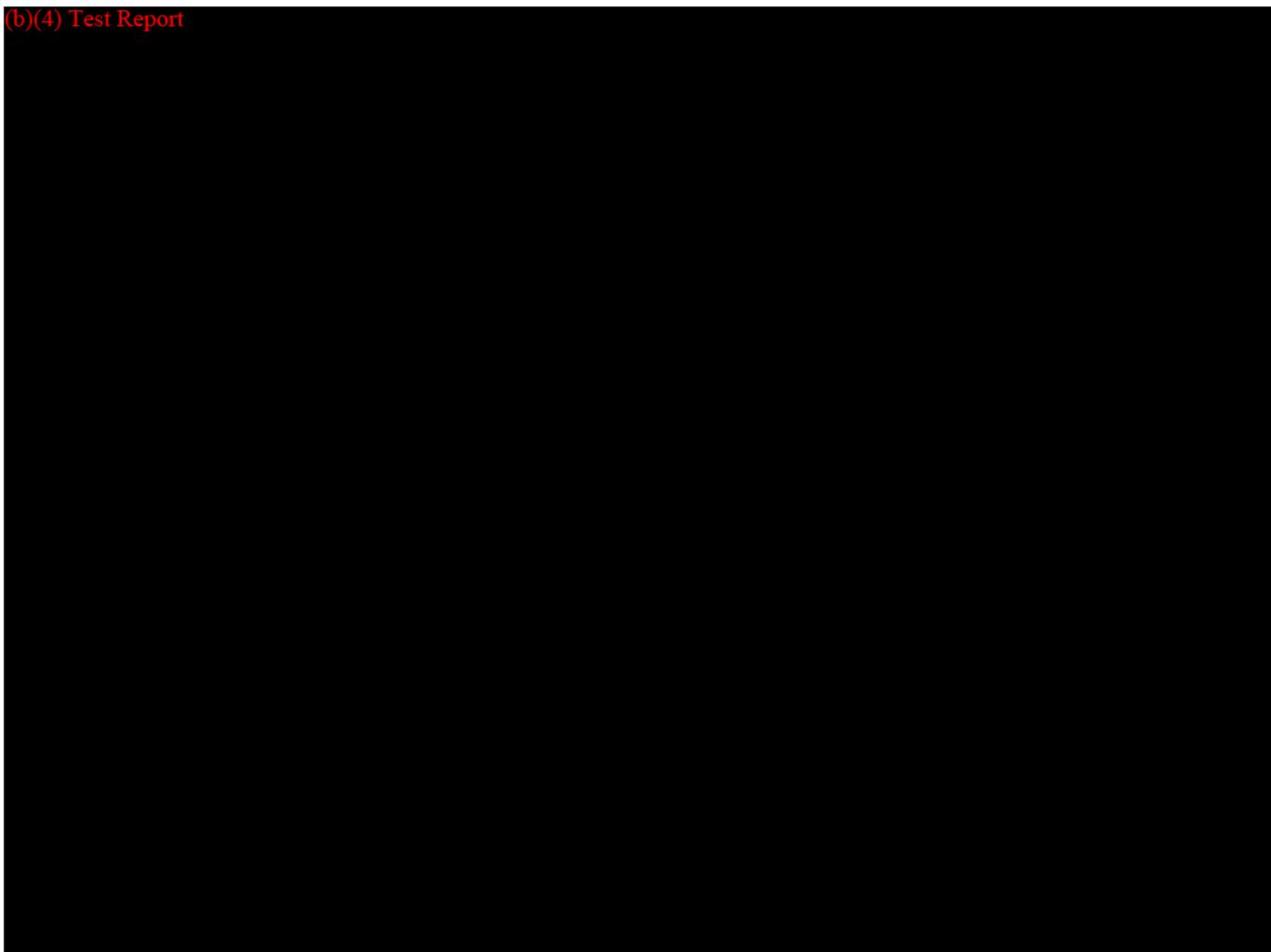
(b)(4) Test Report



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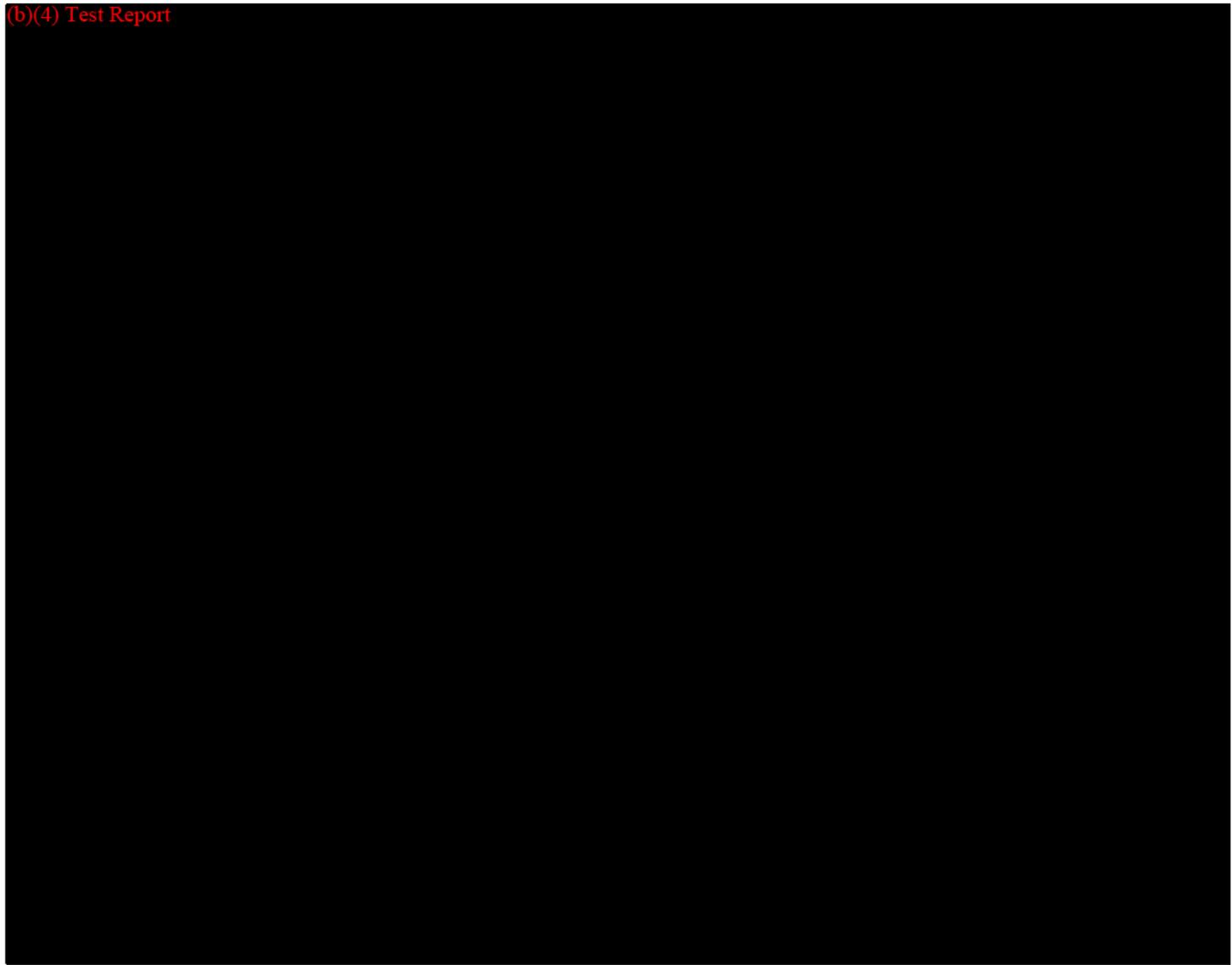


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15. Set Up Photographs

(b)(4) CCI

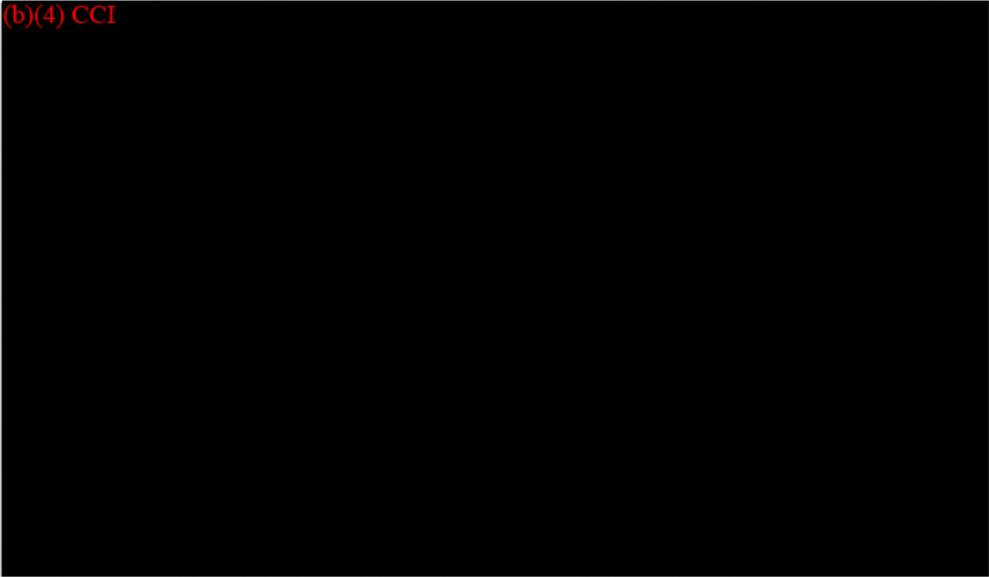


Figure 11. Conducted Emission From AC Mains Test

(b)(4) CCI

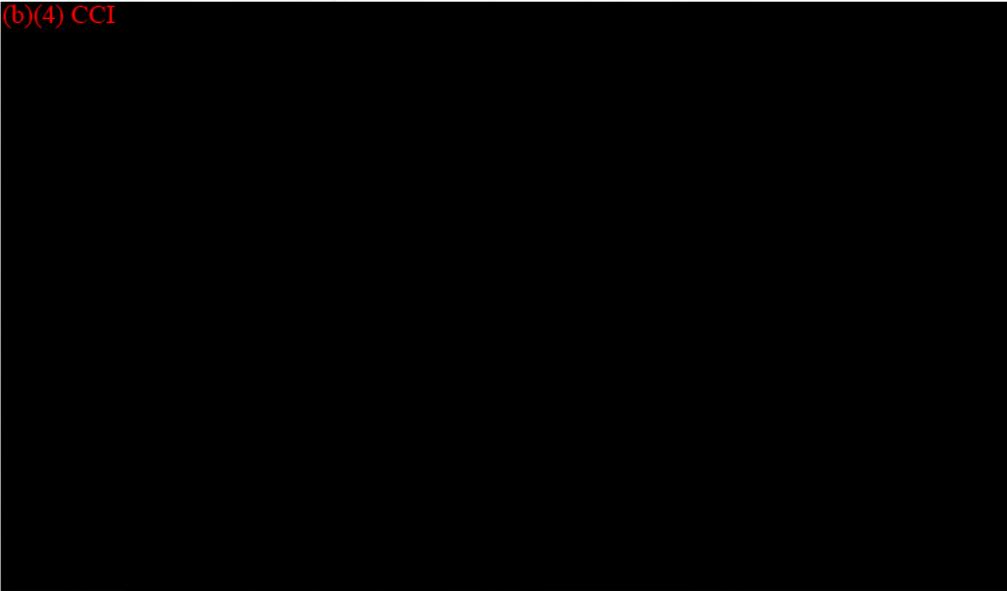


Figure 12. Radiated Emission Test

(b)(4) CCI

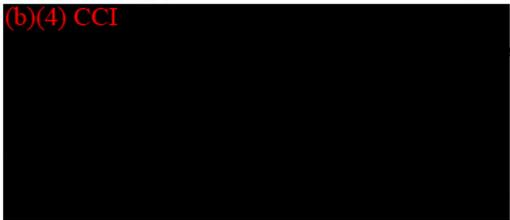


Figure 13 Voltage Fluctuations Test

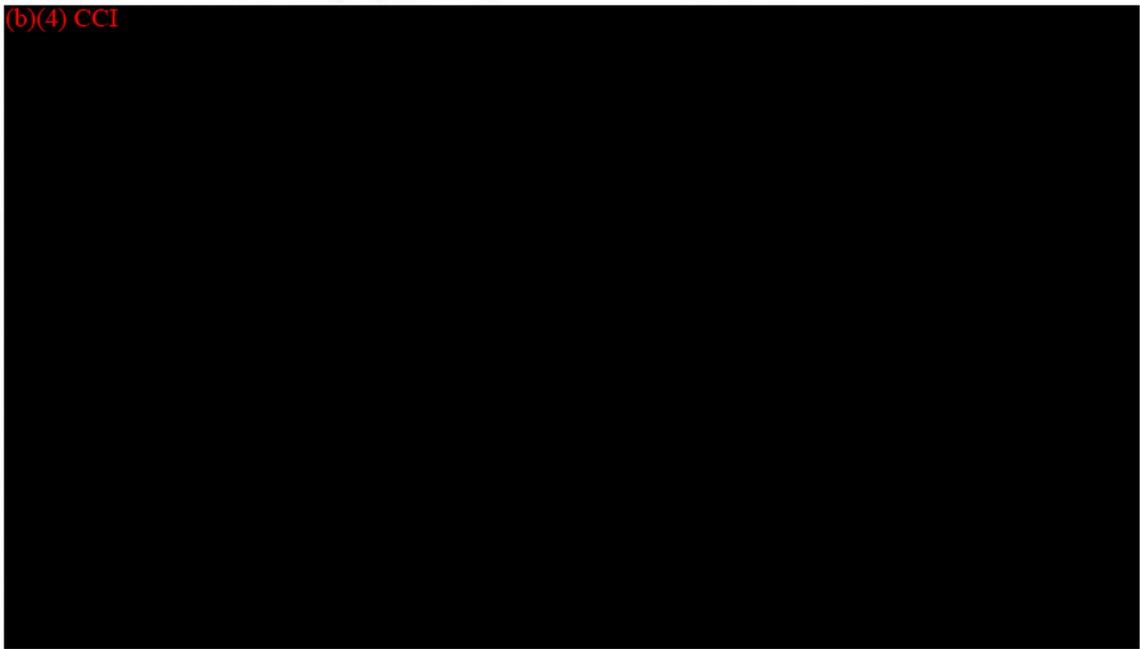
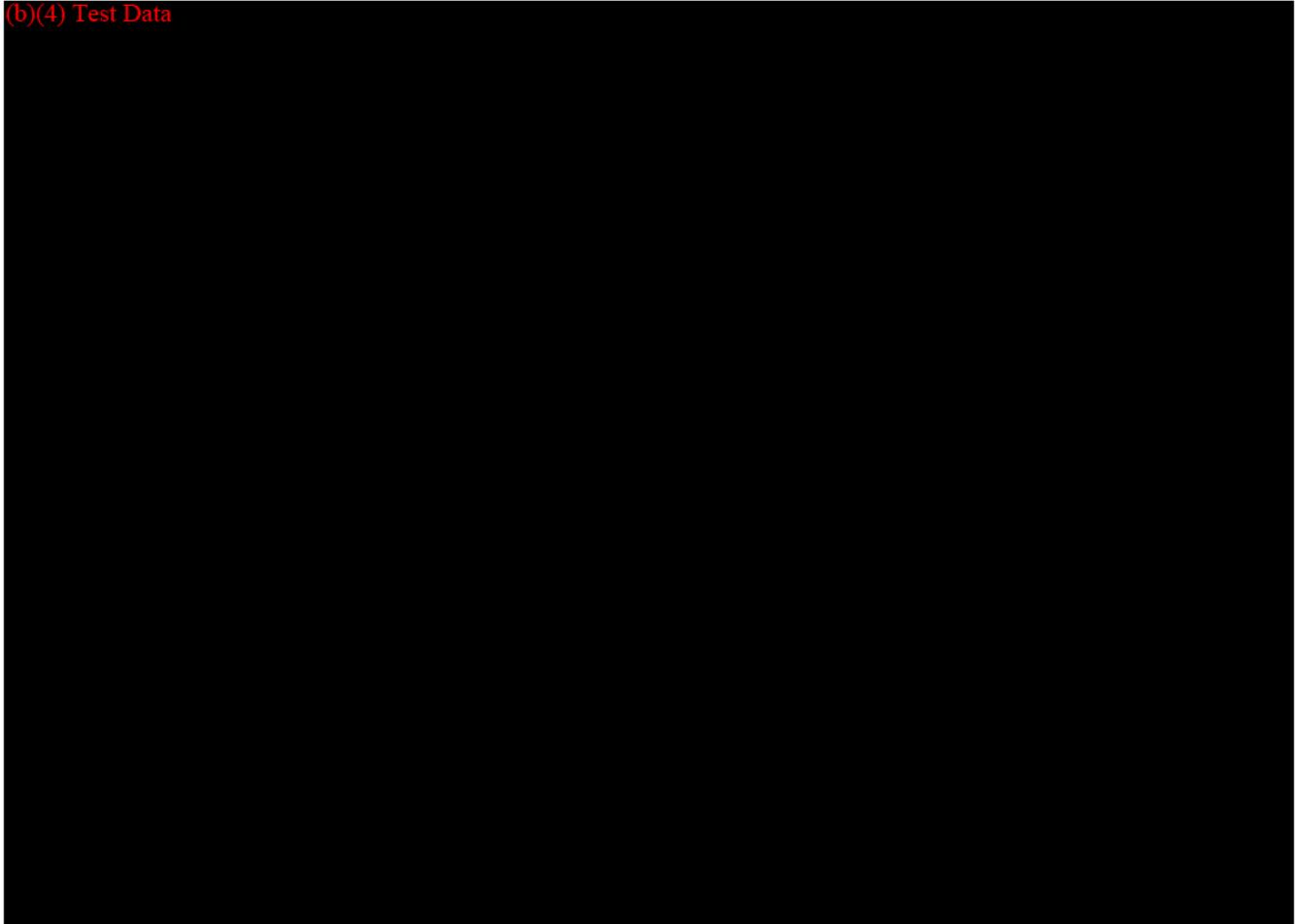


Figure 14. Immunity to Electrostatic Discharge Test

304 17033

18. Performance Testing – Bench

(b)(4) Test Data



Confidential and Proprietary Information
Radiancy no!no! Skin Device™ 510(k) Submission
Section 18 – Performance Testing Bench

Page 1 of 1

Document number: 701E0009
 Document Title: Hazard Management for No-No SKIN device made by Radiancy

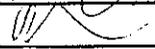
Rev: 03
 Page 1 of 12

RADIANCY®

DESIGNE DOCUMENT

HAZARD MANAGEMENT FOR NO!NO! SKIN DEVICE MADE BY RADIANCY

Rev.	Written by	Date	Description of Change	Approved by	Date
01	Dr. Paul Sofer Philip Solomon	5-Dec-07	First RA at the design beginning	Yigal Harel	5-Dec-07
02	Yigal Harel Philip Solomon	24-Feb-08	Second RA at the design end	Yigal Harel	24-Feb-08
03	Yigal Harel	22-Jul-08	Final RA before Release	Yigal Harel	22-Jul-08

	Name	Title	Date	Signature
Written	Yigal Harel	QA and RA Manager	22-Jul-08	
Approve	Philip Solomon	Head of R&D consumers	22-Jul-08	

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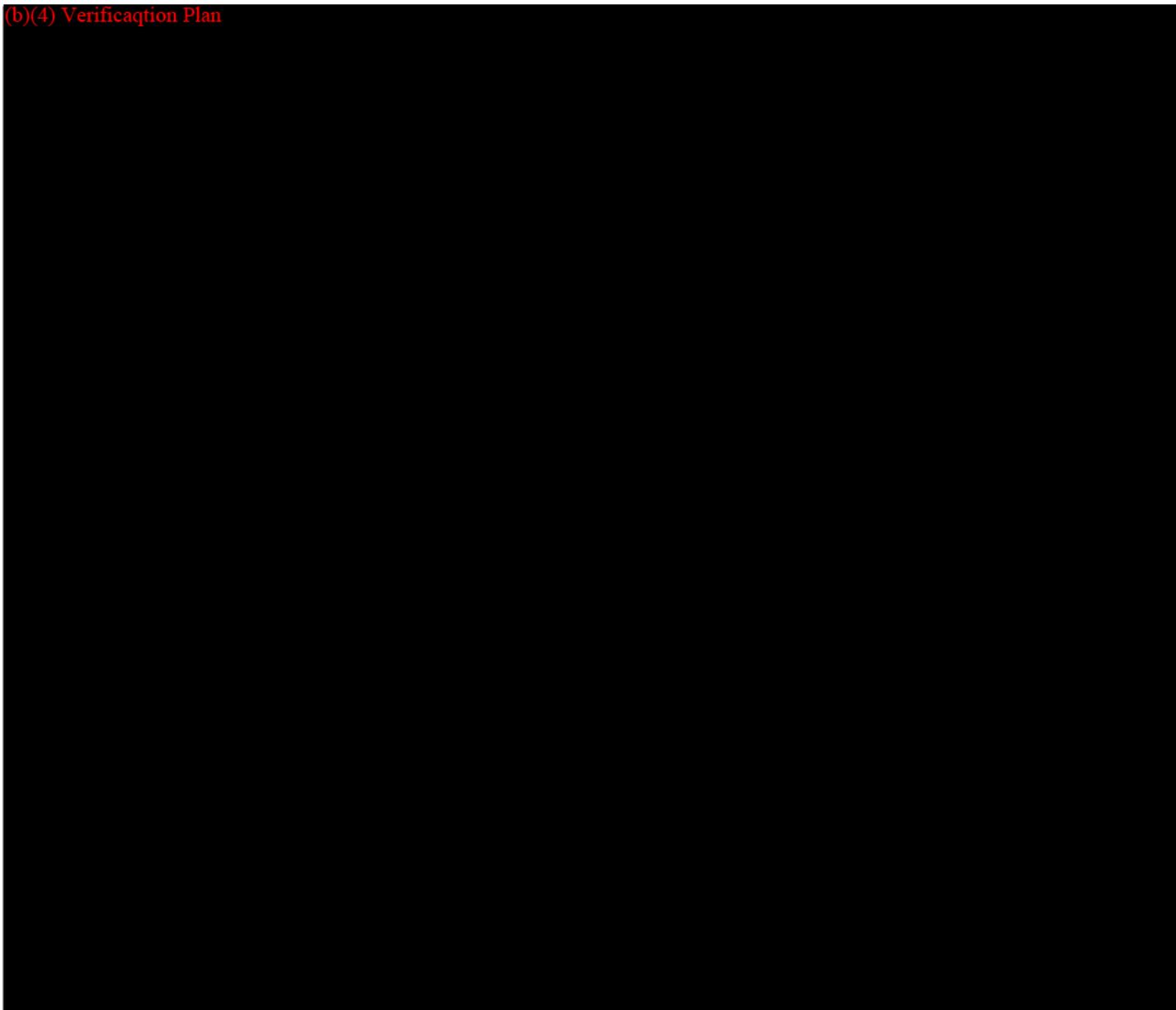
RADIANCY®

VERIFICATION OF R&D PRODUCT

VERIFICATION PLAN FOR

NO!NO!-SKIN™

(b)(4) Verifacqion Plan



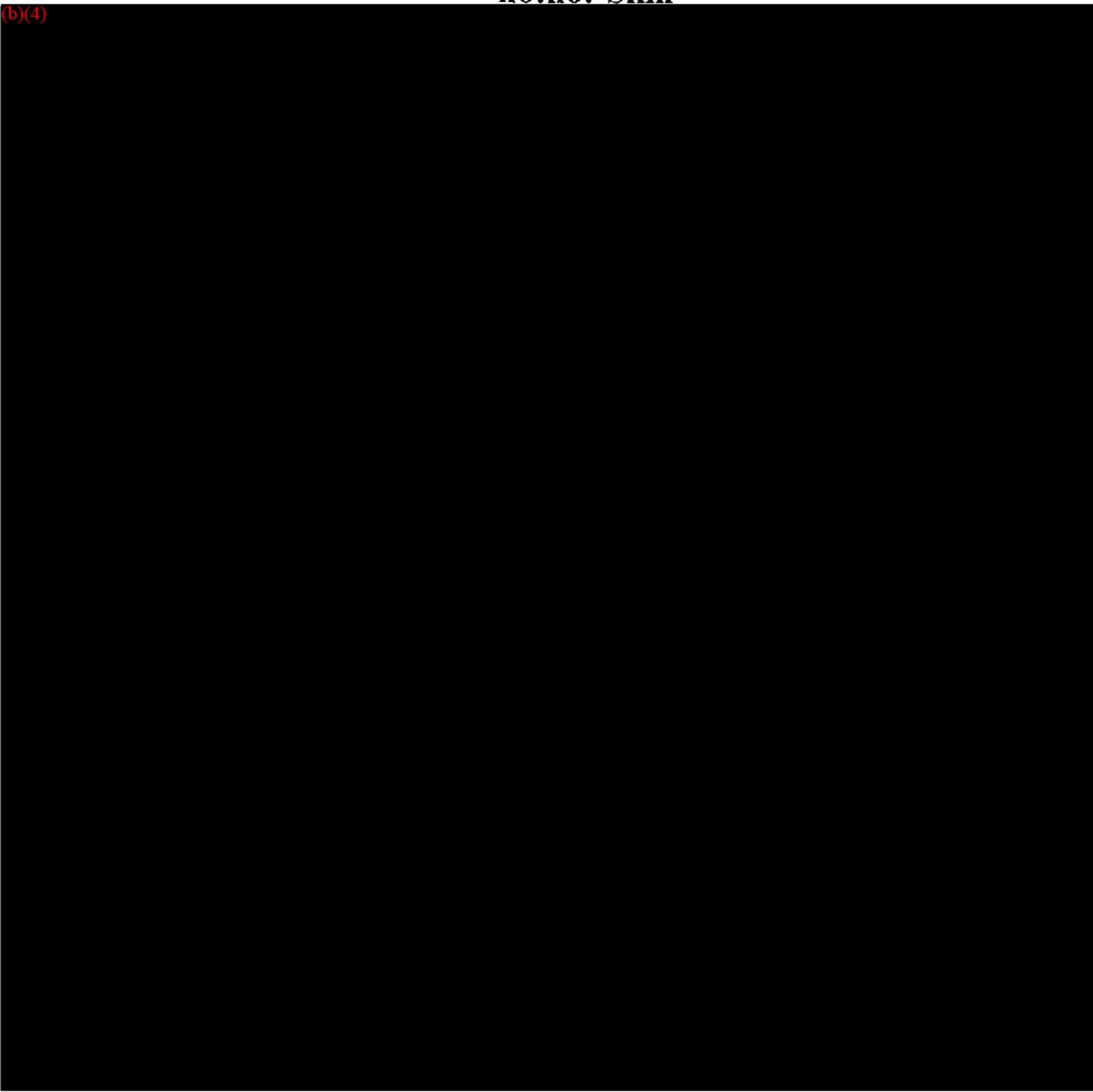
RADIANCY®

DESIGN DOCUMENT

Functionality Test Description (FTD) for

no!no!-Skin™

(b)(4)



19. Performance Testing - Animal

No animal testing was performed and therefore this section is not applicable

RADIANCY™

Protocol for:

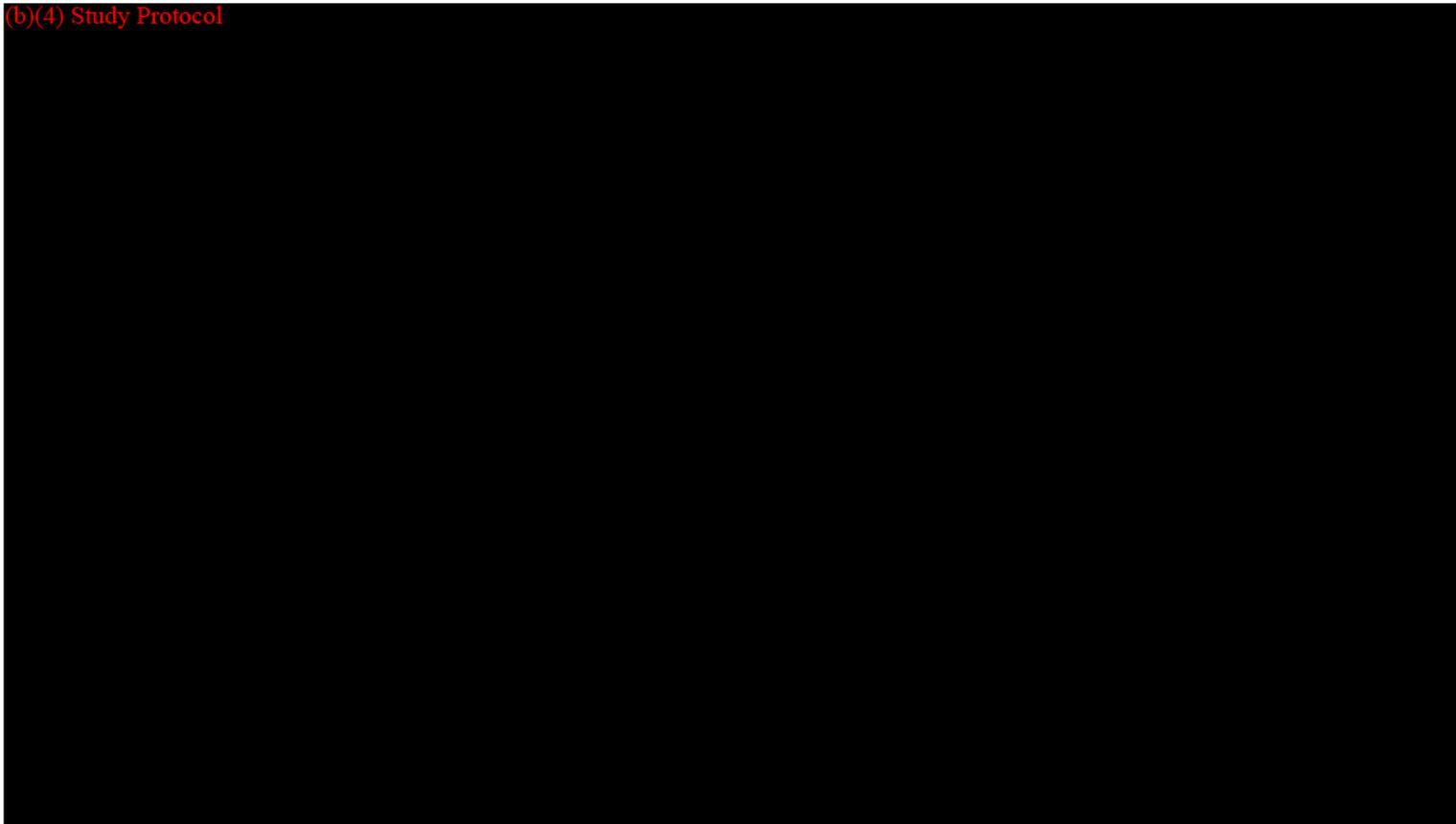
**Radiancy Inc. *no!no! skin*™ Acne Clearance System
User Comprehension Study**

April 3, 2008



(b)(4) Study Protocol

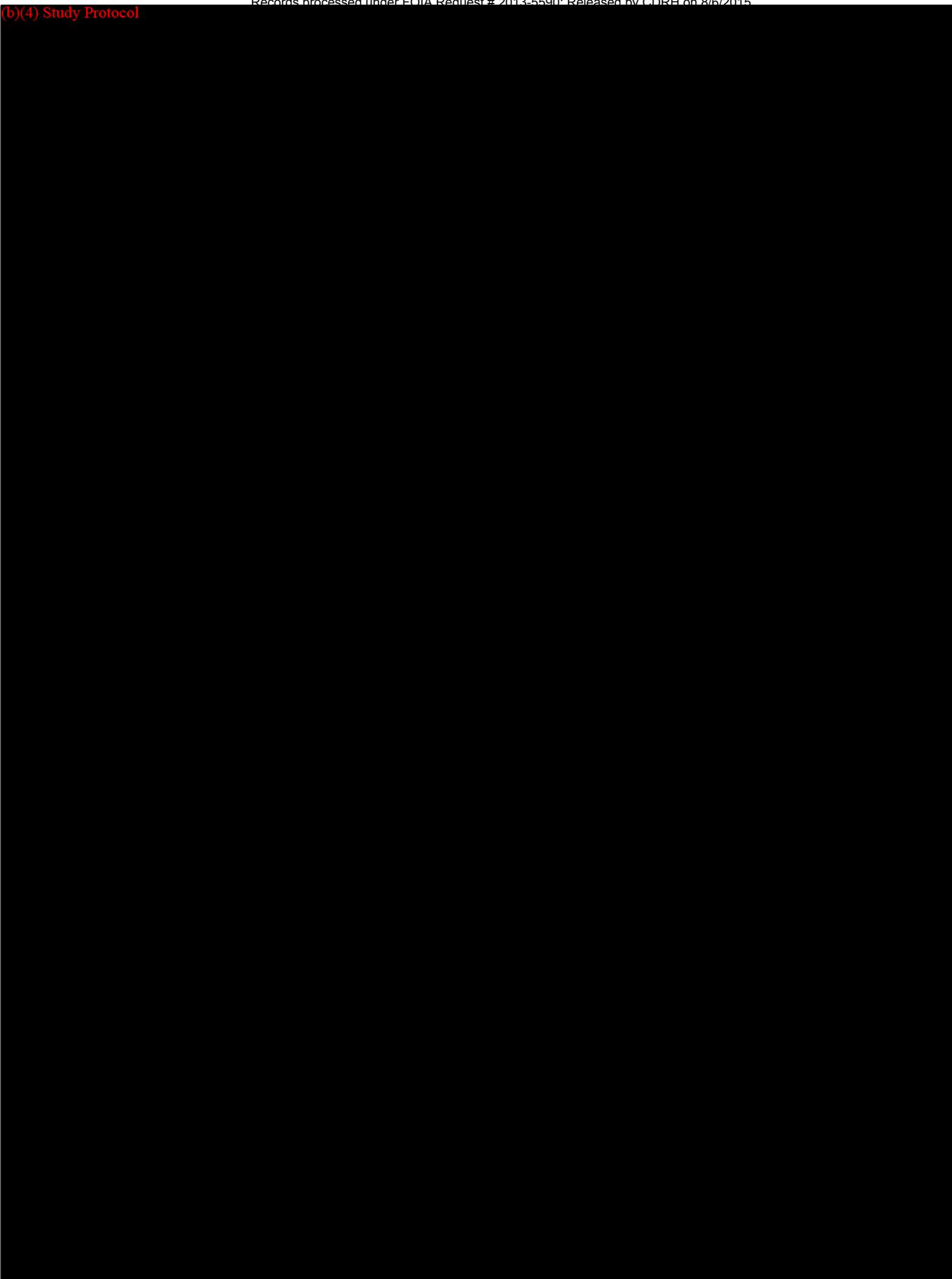
(b)(4) Study Protocol



Radiancy Inc. Proprietary & Confidential Document & Information

Radiancy no!no! Skin™ Device 510(k) Submission **radis 1-3 usability _version 04**
Section 20A – Usability Study Protocol

(b)(4) Study Protocol



Radiancy Inc. Proprietary & Confidential Document & Information

Radiancy no!no! Skin™ Device 510(k) Submission
Section 20A – Usability Study Protocol

radis 1-3 usability _Revision 04

(b)(4) Study Protocol

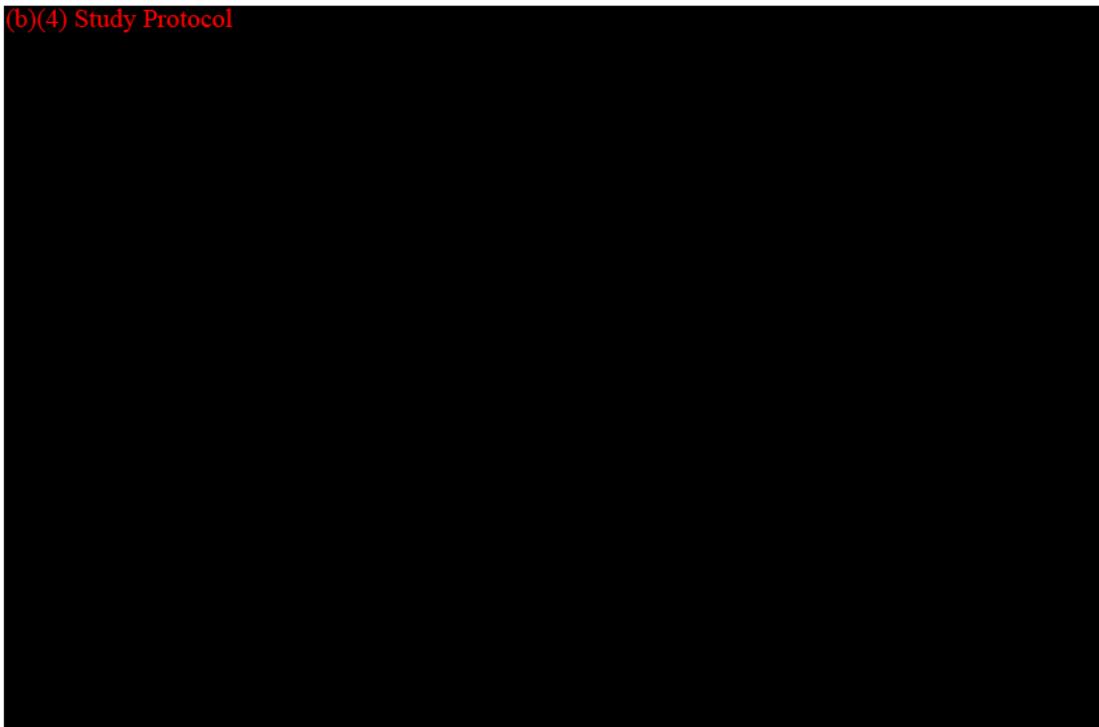




STATISTICAL SUMMARY

RADIANCY INC.—SUMMARY OF THE *NO!NO!*
*SKIN*TM ACNE CLEARANCE SYSTEM
USER COMPREHENSION STUDY

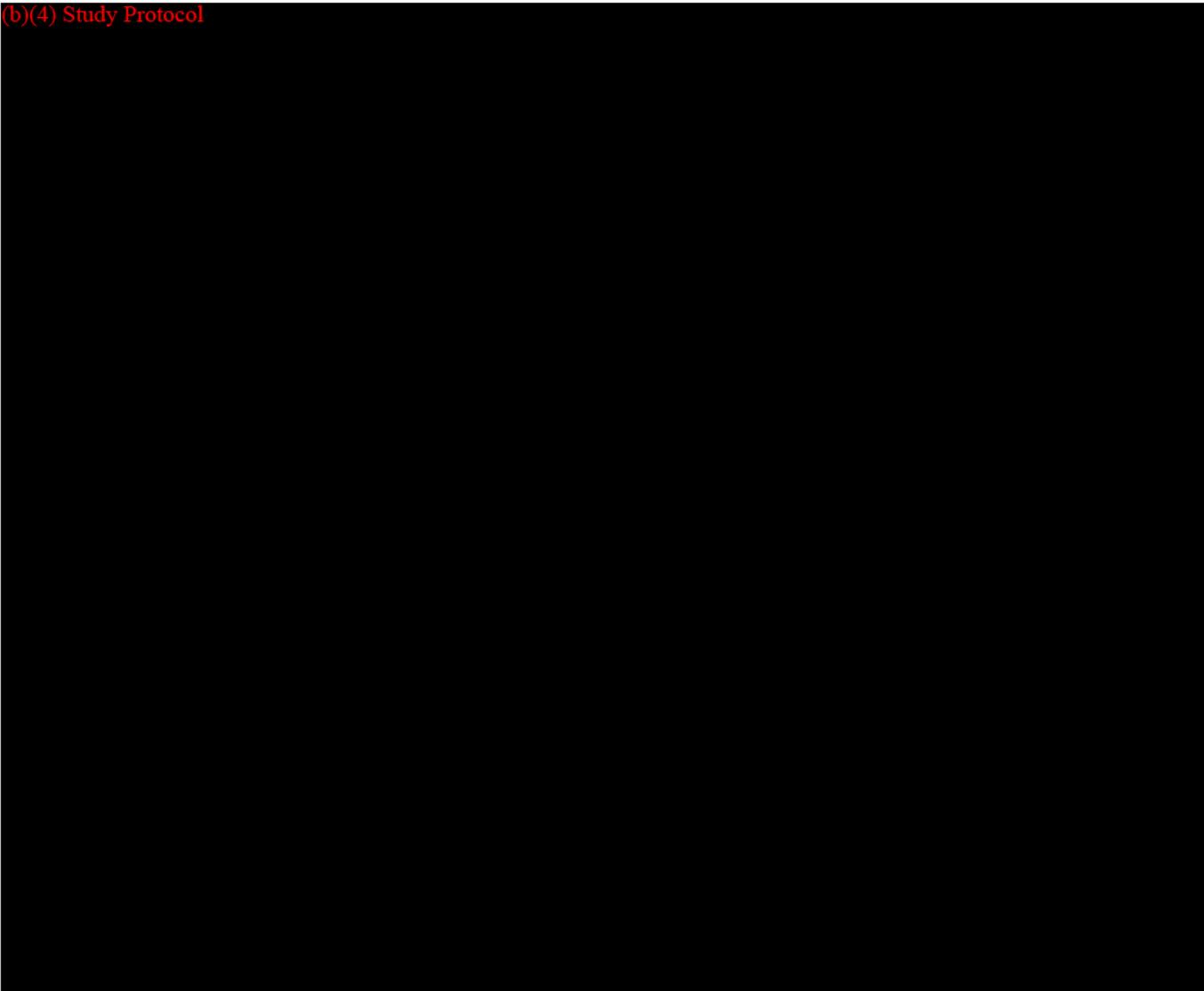
(b)(4) Study Protocol



Proprietary and Confidential Information
Radiancy no!no! Skin Device™ 510(k) Submission
Section 20C – Usability Study Statistics Report
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3. Summary and Conclusions

(b)(4) Study Protocol



Proprietary and Confidential Information
Radiancy no!no! Skin Device™ 510(k) Submission
Section 20C – Usability Study Statistics Report
12 of 12 Page

RADIANCY™



Clinical Study Protocol for:

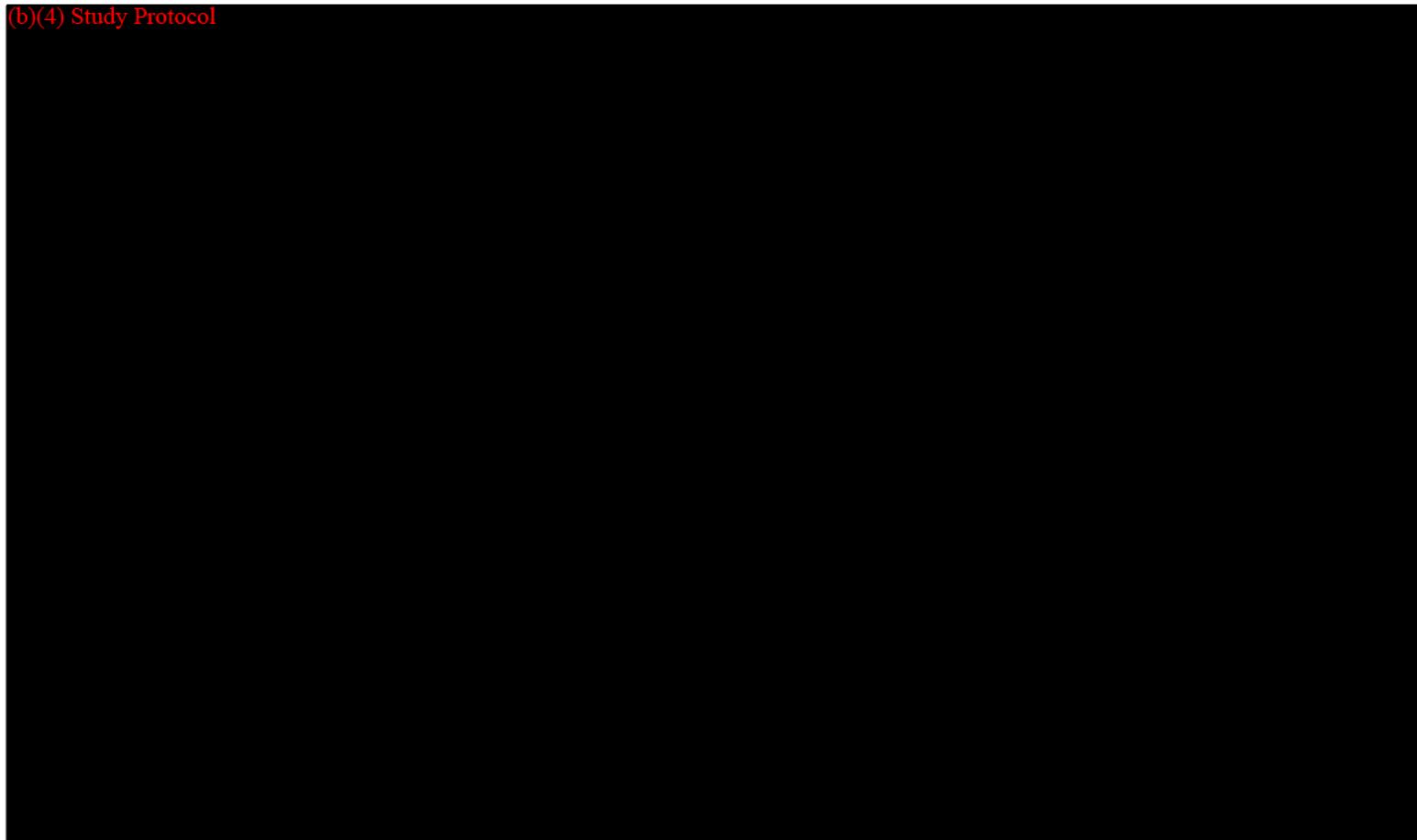
Treatment of Mild to Moderate Acne Vulgaris
Using *no!no! skin*™ Home-Use OTC Device

(b)(4) Study Protocol



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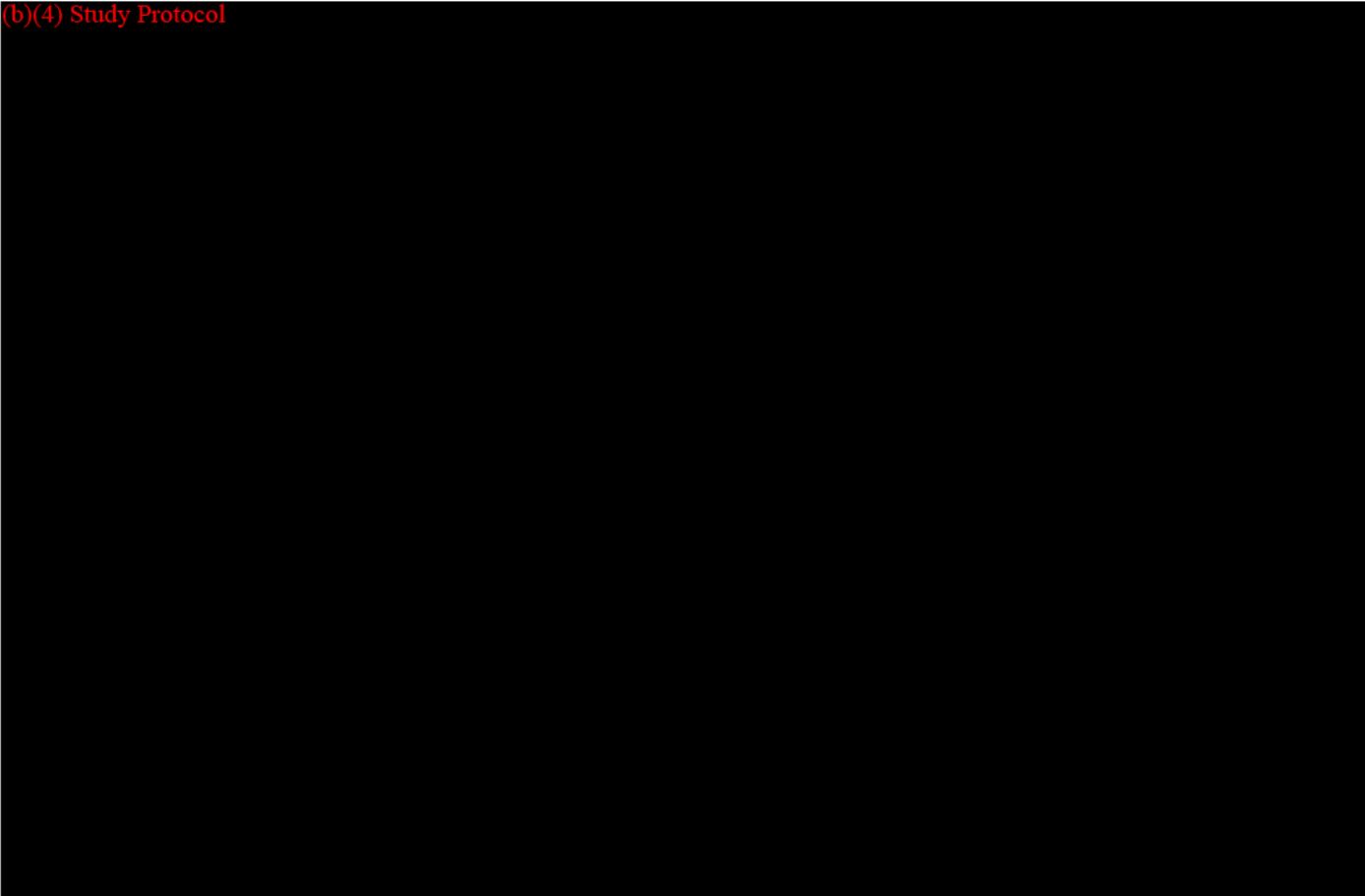
(b)(4) Study Protocol



(b)(4) Study Protocol



(b)(4) Study Protocol



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radis 1-3_REV_04

Radiancy no!no! Skin™ Device 510(k) Submission
Section 20D – Clinical Study Protocol

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Study Protocol



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radis 1-3_REV_04

(b)(4) Study Protocol



**Proprietary & Confidential Document & Information of
radis 1-3_REV_04**

Radiancy no!no! Skin™ Device 510(k) Submission
Section 20D - Clinical Study Protocol Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

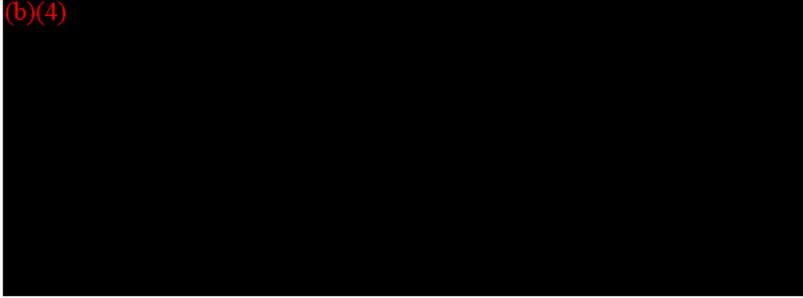
482

Proprietary and Confidential Information

Radiancy no!no! Skin Device™ 510(k) Submission
Section 20E – Clinical Study Summary

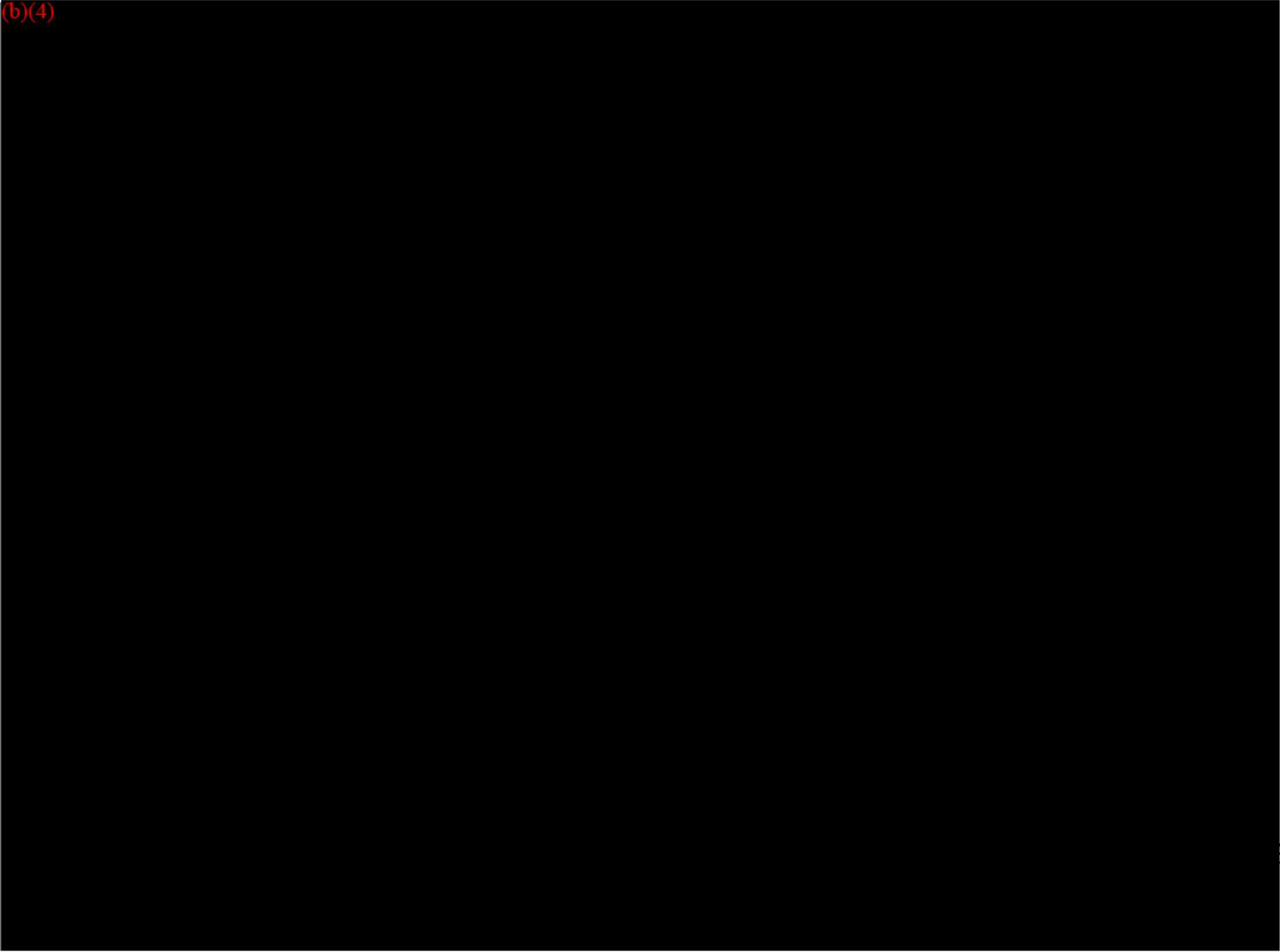
Page 5 of 14

no!no! Skin™ (b)(4)



STATISTICAL SUMMARY

RADIANCY INC.—SUMMARY OF THE *NO!NO!*
SKIN™ ACNE CLEARANCE SYSTEM
PIVOTAL CLINICAL STUDY



510(k) Premarket Notification
Tyrell, Incorporated Zeno™ Acne Device

JUN 1 - 2005

K043377

510(k) SUMMARY
TYRELL, INCORPORATED – Zeno Acne Device

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Sponsor's Name and Address: Tyrell, Inc.
515 West Greens Road, Suite 725
Houston, TX 77067
Telephone: (281) 880 - 6541
Facsimile No. (281) 880 - 6702

Submitter Information: Darla J. Elkin
Director, Regulatory Affairs, Quality Systems
SYNERGOS, Inc.
2202 Timberloch Place, Suite 230
The Woodlands, TX 77380-1109
Telephone No.: (281) 367-6655
Facsimile No.: (281) 367-9679

Device Trade Name: Zeno™
Common Name: Acne Treatment Device

Classification: Class II

Predicate Devices: National Biological Corporation
Derma-Wand
K982082

CureLight Ltd.
ClearLight Phototherapy System, Model CI 420
K013623

Radiancy (Israel) Ltd.
Radiancy Acne System With ClearTouch Light Unit A
K032205

Description of the Device

Zeno is a portable hand-held device that produces accurately controlled low level sustained heat for use in treating dermatological disorders, specifically, mild to moderate acne. Individual acne blemishes are treated for a preset time of 2 ½ minutes at a preset temperature. The treatment tip is made from a biocompatible material and delivers the specific low-level heat to the individual acne blemish. The device is powered by rechargeable AAA nickel-metal hydride batteries.

510(k) Premarket Notification
Tyrell, Incorporated Zeno™ Acne Device

Indications for Use

Zeno is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Performance Data

Preclinical and clinical testing performance testing was conducted with Zeno.

Preclinical Testing

In vitro testing demonstrated significant sensitivity of *p. acnes* bacterial cells to the effects of sustained low-level heat.

Biocompatibility testing of the tip material was conducted in accordance with the ISO 10993 Biological Testing of Medical and Dental Materials and Devices and the tip material is considered biocompatible.

Zeno was tested for EMI in accordance with the IEC 60601-1 standard. Zeno operates within the EMI emission, susceptibility and static discharge levels specified in the IEC 60601-1 standard.

Clinical Testing

Clinical testing was conducted in both a controlled practitioner office environment and a consumer home-use environment and submitted as part of the 510(k) application to confirm that Zeno is as safe and effective as the predicate device. The controlled clinical study design was a randomized, doubled-blinded study.

Substantial Equivalence

The Zeno and its predicate devices are all devices that use either light or heat to treat the dermatological condition of mild to moderate acne by exposing the surface of the skin to the light at precise wavelengths and temperatures or heat at precise temperatures. Although there are differences in the technological characteristics of the Zeno and its predicate devices, those differences do not raise new questions of safety or efficacy. Another difference is Zeno will be available over the counter (OTC) versus the predicate device which is prescription use only however there are no new safety or efficacy concerns regarding this use as evidenced by the clinical testing that was conducted on Zeno. Thus, Zeno is substantially equivalent to the predicate device for treatment of mild to moderate acne.

Conclusion:

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the proposed device has been shown to be safe and effective for its intended use.



JUL 13 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tyrell, Inc.
c/o Ms. Darla J. Elkin
Director, Regulatory Affairs, Quality Systems
Synergos, Incorporated
2202 Timberloch Place, Suite 230
The Woodlands, Texas 77380

Re: **K043377**

Trade/Device Name: Zeno

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and
in dermatology

Regulatory Class: II

Product Code: GEX

Dated: March 2, 2005

Received: March 3, 2005

Dear Ms. Elkin:

This letter corrects our substantially equivalent letter of June 1, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 - Ms. Darla J. Elkin

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. ✓

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


Miriam Provost, Ph.D.
Miriam Provost, Ph.D.

Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Premarket Notification
Tyrell, Incorporated - Zeno™ Acne Device

Indications for Use

510(k) Number: K043377

Device Name: Zeno

Indications For Use: Zeno is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

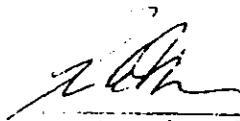
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

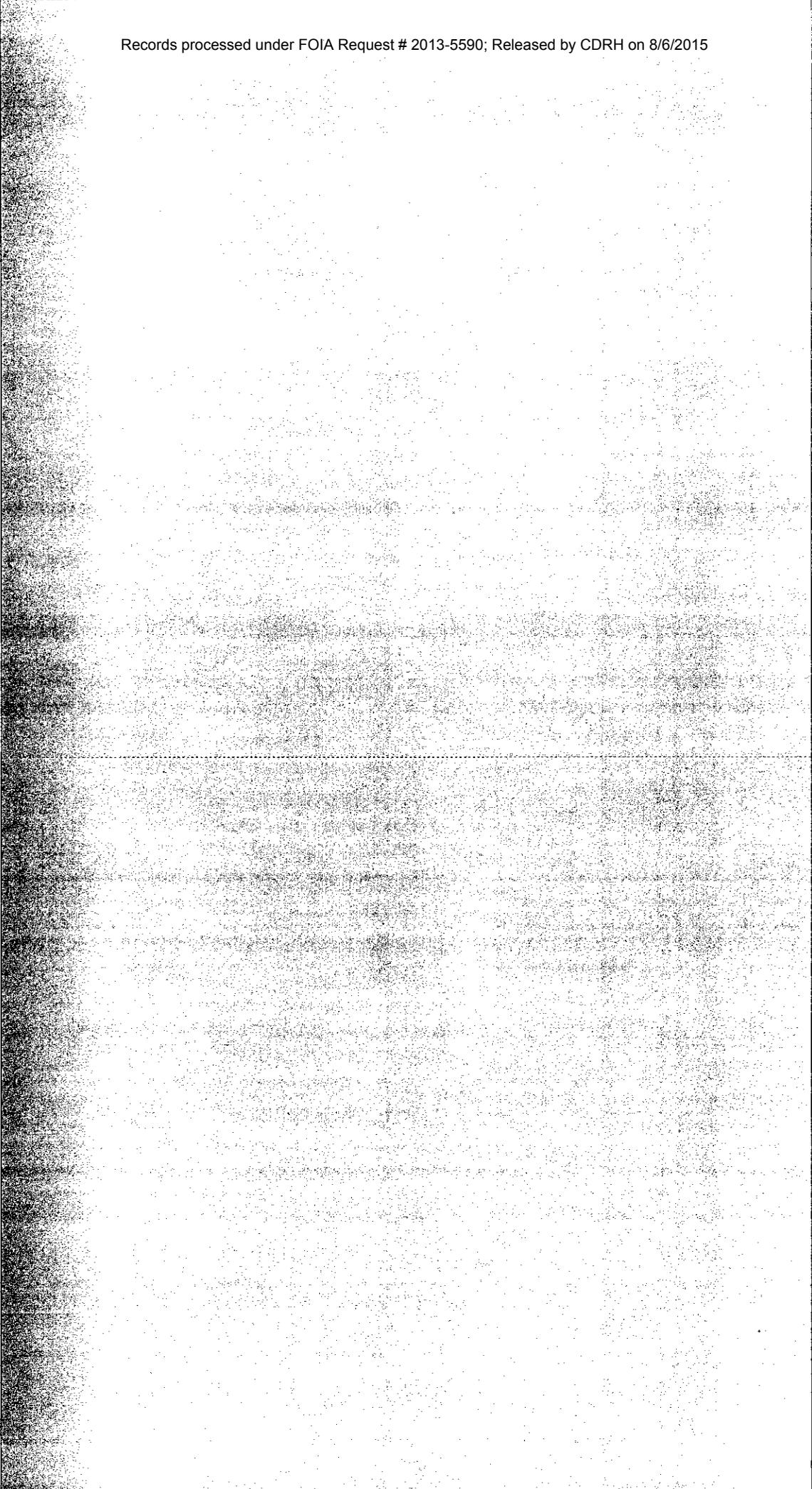


Page 1 of 1

Director (Sign. Off)
Division of General, Restorative
and Neurological Devices

K043377

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Section 21B
page 1

Table of Contents

1	Welcome!
2	What Is Zeno and How Does It Work?
3	Indications for Use
4	About Zeno and Acne
4	Acne Simplified
5	Treatment Recommendations and What to Expect
6	Using Zeno
7	Product Diagram
7	How to Use Zeno
10	Charging Your Zeno's Batteries
11	Treatment Tip Life Indicators
12	Replacing the Treatment Tip Cartridge
13	Warnings and Precautions
13	Contraindications (Reasons Not to Use)
15	Warnings
15	Precautions
16	Risks and Benefits
17	Caring for Zeno
17	Care and Maintenance
18	Helpful Hints
19	Troubleshooting
22	Use Outside the United States
22	Storage
22	Disposal
22	The Zeno Money-Back Guarantee
23	Limited One-Year Warranty

Symbol	Explanation
	Manufacturer
	European Authorized Representative
SN	Serial Number
	Date of Manufacture
	Caution, Consult Accompanying Documents

Read all instructions before use.



515 W. Greens Road, Suite 725
Houston, Texas 77067 USA

+1.281.880.6541 Inside the USA: 888-4MY-ZENO or 888-469-9366
www.myzeno.com

Welcome!

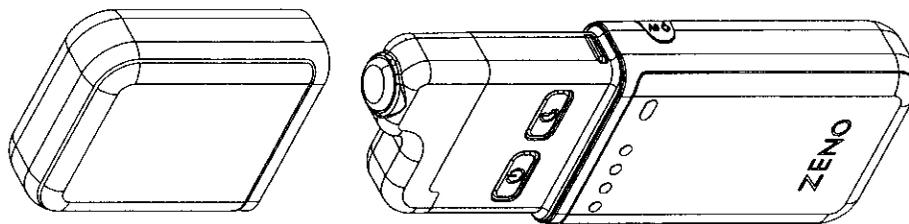
Pimples! Who needs them? Now, Zeno® puts you back in charge of your skin's appearance by giving you a quick and effective way to bring pimples under control.

Zeno is dermatologist-recommended and works best **at the first signs of a new pimple**. If you know from past experience that a sore spot or red bump may turn into a pimple, reach for your Zeno. Clinical trials have shown that pimples treated with Zeno can fade or disappear **within just 24 hours!**

Zeno is a clinically proven medical device, not a medication. Unlike strong medicines, Zeno has been shown in tests to have no significant side effects. So use Zeno confidently. But don't abandon your regular skin care routine. Zeno does not replace good skin hygiene. It simply takes over when pimples overwhelm your skin's natural balance.

With two to three treatment cycles of 2½ minutes, spread over 12 to 24 hours, Zeno helps shorten the pimple's life cycle. Your face will look clearer, faster. What's more, the shorter the life of a pimple, the less chance it has to leave a scar.

Tyrell, Inc. is proud to offer you the most advanced breakthrough in acne pimple treatment. We are so confident in your satisfaction that we're offering you a **money-back guarantee**. For details, please refer to page 22 of this manual or visit www.myzeno.com.



Important Reminder: Your Zeno batteries must be fully charged for at least 6 hours before initial use. For safety reasons, Zeno will not operate when plugged into the Wall Charging Plug.

(See page 6 for complete product diagram.)

What Is Zeno and How Does It Work?

The Device: Zeno is a battery-powered medical device used to treat individual mild to moderate acne pimples. Zeno has a built-in computer that controls a Treatment Tip Cartridge which adjusts to your skin to make sure each treatment puts the right amount of energy into each pimple. Also, the computer tells you what the battery charge level is and how many treatment cycles are left in the Treatment Tip Cartridge.

The Treatment Tip Cartridge: The Treatment Tip Cartridge has a memory chip to make sure the right amount of energy is given. It also controls the number of treatments, and makes sure the device is safe at all times. The Treatment Tip Cartridge is programmed with a specific number of treatment cycles (as shown by the number on the top of the cartridge). Each treatment cycle is 2½ minutes. The Treatment Tip Life Indicators show how many treatments are left. (See Treatment Tip Life Indicators section.) It is easy to replace the Zeno Treatment Tip Cartridge that came with your Zeno. (See Replacing the Treatment Tip Cartridge section.) You can buy additional cartridges where you purchased Zeno or at www.myzeno.com.

Indications for Use

Zeno is a medical heat dose treatment device for the treatment of individual acne pimples in people with mild to moderate inflammatory acne. If you have severe acne or a high number of pimples, you may need other treatments. Ask your health care professional.

Zeno should not be used by people with severe acne. Blackheads and whiteheads are not pimples, and Zeno will not work on them. **The key to getting the best results is to treat pimples as early as possible.**

Acne Type	Description	Zeno
No acne	Total absence of acne	Not Necessary
Subclinical acne	Few blackheads and whiteheads; visible only in close examination	No
Comedonal acne	Blackheads and whiteheads with slight inflammation (red)	No
Mild acne	Several inflamed (red) pimples	Yes
Moderate acne	Many inflamed (red) pimples and pustules* (visible accumulation of pus in skin)	Yes
Severe nodular acne	Inflamed (red) pimples and pustules (visible accumulation of pus in skin) with several deep nodular lesions (solid mass of skin like a knot, can be raised or felt under the skin)	No
Severe cystic acne	Many nodular cystic lesions with scarring	No

*Note: Zeno has not been tested or proven to work on pustules, as these blemishes are past the early stage.

- Zeno will not work when used on blemishes such as blackheads or whiteheads.
- Zeno should not be used by persons with severe nodular or cystic acne.

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Acne Simplified

Acne is a disorder of the skin caused by infected hair follicles and skin glands. Hormones can cause your skin to produce excessive sebum (skin oil) and increase the proteins that slough off cells in the skin's outer layer. When excess sebum, skin cells, and skin proteins clump together, they plug up the opening of a follicle. These plugged follicles create an ideal place for *Propionibacterium acnes* (*P. acnes*) bacteria to multiply beyond normal levels. A pimple occurs when *P. acnes* gets out of balance. Zeno helps restore that balance and brings *P. acnes* back to normal levels.

Blackheads and whiteheads are closer to the surface of the skin and are not considered pimples. They can be recognized by the black or white center visible at the surface. Pimples, however, are more recognizable by their redness, swelling and/or tenderness to the touch.

Treatment Recommendations and What to Expect

Use Zeno at the first sign of a pimple. Follow the instructions in the How to Use Zeno section on page 7. Clinical studies show that many pimples get better after one treatment. This means either the blemish gets smaller or the soreness of the blemish decreases. If necessary, treat the same pimple again after 4 to 12 hours. You may treat the pimple a third time 4 to 12 hours later. Consider treating once in the evening, once again in the morning, and a third treatment the following evening if necessary.

After treatment, you may see redness where the Treatment Tip touched your skin. This is normal and should fade within a few hours. Within 4 to 24 hours of the first treatment of a pimple, you should notice that the pimple gets smaller, less red and/or less tender.

Following the treatment instructions found in this manual, 90% of the participants in a clinical study reviewed by the FDA found that pimples treated with Zeno faded or disappeared within just 24 hours! That compares to just 37% for pimples treated with a placebo.

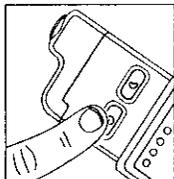
Don't pick or squeeze the pimple, as this will not help the healing process and could lead to skin rupture and scarring.

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How to Use Zeno

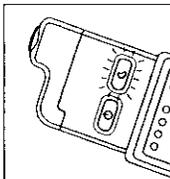
Important Reminder: Your Zeno batteries must be fully charged for at least 6 hours before initial use. For safety reasons, Zeno will not operate when plugged into the Wall Charging Plug. You may also want to review the Helpful Hints on page 18 prior to your first use.

Gently remove the cover ❶. Make sure the Treatment Tip Cartridge ❷ is installed (your new Zeno has one already installed). Using a clean cloth, wipe the Treatment Tip ❸ with warm soapy water or alcohol (always clean the Treatment Tip before use).



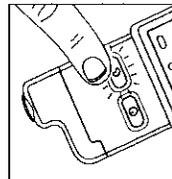
STEP 1 Press the Power Button ❸

A three-tone Power On sound indicates Zeno is starting. The front panel lights will turn on, and the Treatment Activation Button ❹ will glow amber.



STEP 2 Await flashing green light (approx. 1 minute)

The flashing green light, accompanied by a two-tone Ready sound, indicates that Zeno has completed all safety checks, has reached the correct target treatment temperature, and is ready for use.

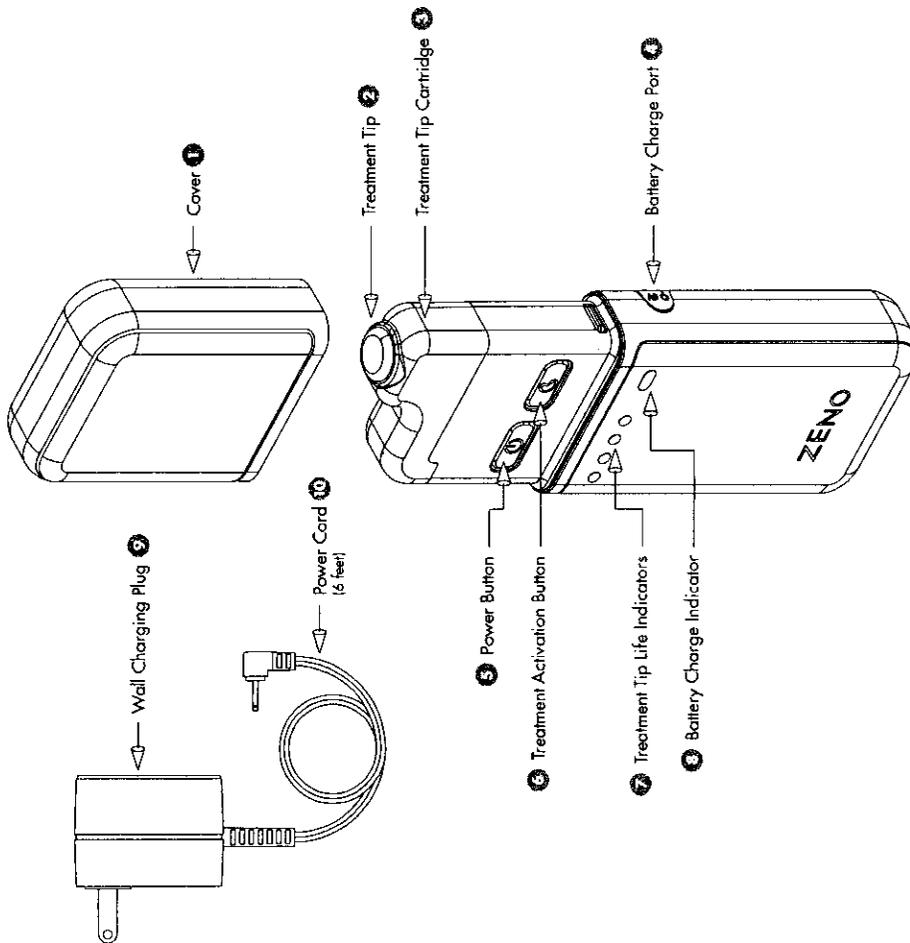


STEP 3 Press the flashing green light

Pressing the Treatment Activation Button ❹ changes it from flashing to continuous green. A five-tone ascending Treatment Start sound indicates Zeno is initiating a treatment cycle.

❶ Refer to Product Diagram on page 6

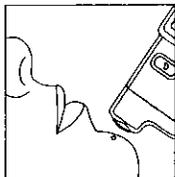
Product Diagram



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STEP 4 Place and hold on pimple

Gently place the Treatment Tip 2 directly on the pimple (pushing hard does not affect treatment and may make temporary redness last longer). Every 30 seconds the single-tone Treatment Pacer will sound to help you track the treatment cycle. After 2½ minutes, the Treatment Activation Button (G) turns amber and a five-tone descending Treatment Complete sound indicates treatment is done. For the best results, keep the Treatment Tip 2 on the pimple for the entire cycle.



When the treatment is complete, remove Zeno from the pimple. Depending upon your skin, you may notice some temporary skin redness around the treatment area. This redness is normal and should reduce over the next few hours. See the Precautions section on page 15.

If you want to treat another pimple, wait about 10 seconds until the Treatment Activation Button (G) again flashes green, then start again at Step 3. When you have finished all treatments (limited by a Safety Delay Feature to 3 treatments in a row), press the Power Button (U). A three-tone Power Off sound will let you know Zeno is turned off. The Safety Delay Feature releases the Zeno after 2 minutes, and your Zeno can then be used for additional treatments.

Note:

- Zeno will turn itself off if a treatment cycle is not started within 35 seconds of the Ready signal (when the Treatment Activation Button (G) flashes green).
- Zeno gives multiple beeps after 25 seconds to alert you that it will power down if the Treatment Activation Button (G) is not pressed within 10 seconds.
- If Zeno does power down, restart it by pressing the Power Button (U). Wait for the Treatment Activation Button (G) to turn from amber to flashing green, then go to Step 3.

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Treatment Tip Life Indicators

The replaceable Treatment Tip Cartridge that came with your Zeno is programmed with a specific number of treatment cycles. The Treatment Tip Life Indicators show you the number of treatments left:

- 4 blue lights 100%–76% of treatments remain
- 3 blue lights 75%–51% of treatments remain
- 2 blue lights 50%–26% of treatments remain
- 1 blue light 25% or less of treatments remain
- 1 blue light flashing 5 treatments or fewer remain
- 4 blue lights flashing no treatments remain or tip removed

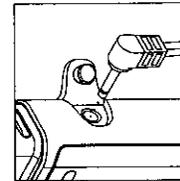
To avoid wear of the Treatment Tip connector pins, do not remove the Treatment Tip Cartridge until it is ready to be replaced.

Refer to Product Diagram on page 6

Charging Your Zeno's Batteries

The Battery Charge Indicator glows blue when the battery is fully charged. It flashes blue when the battery charge is low. When the battery is out of charge, the Battery Charge Indicator no longer glows.

Your Zeno batteries must be fully charged for at least 6 hours before initial use. **You should keep Zeno fully charged when not in use.** (Partial charging will not damage the nickel metal hydride batteries.) Recharge the batteries if the Battery Charge Indicator flashes blue after Power On. Zeno will not begin a treatment cycle if the battery is too low.



To charge Zeno, plug the Wall Charging Plug into a standard household electrical outlet. Make sure that the Wall Charging Plug, which is rated at an input of 120V at 60 cycles, matches the local electrical input before use. Voltage converters or plug adapters DO NOT guarantee the proper voltage. If the Wall Charging Plug enclosed is labeled with 100-240V at 50/60 cycles, it is safe to use with most domestic U.S. electrical outlets as well as when traveling outside the United States. Never force the plug into an outlet.

For safety reasons, Zeno will not operate while plugged into the Wall Charging Plug.

Refer to Product Diagram on page 6

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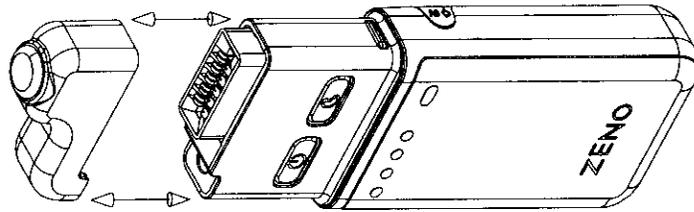
Replacing the Treatment Tip Cartridge

The Zeno Treatment Tip Cartridge is programmed with a specific number of treatment cycles, indicated by the number inscribed onto the top of the cartridge. Once the treatment cycles have been exhausted, the Treatment Tip must be replaced. Replacement Tip Cartridges are available where you purchased Zeno or at www.myzeno.com.

To remove the Tip Cartridge, first ensure that Zeno is powered off. Hold Zeno upright in one hand and pull the Tip Cartridge up and off Zeno with the other hand. Take care to pull firmly and directly upward to avoid damaging the microprocessor interconnection pins on your Zeno. The Zeno Treatment Tip once exhausted has no value; please properly dispose of the exhausted Tip Cartridge.

To attach a new Tip Cartridge, we recommend that you place Zeno on a flat surface and hold it upright in one hand with the buttons and Data Information Panel facing you. Holding the replacement cartridge in the other hand, align the cartridge so that the Treatment Tip is to the right and above the Treatment Activation Button. Press the cartridge straight down onto Zeno, taking care to press firmly and directly down to avoid damaging the cartridge connector or internal connections on Zeno. **Do Not Force!** Your Zeno is a carefully manufactured high-quality device; the tip should attach easily. If it does not, recheck your alignment.

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Contraindications (Reasons Not to Use)

- Use Zeno only for pimples. Do not use Zeno for skin lesions such as moles, warts or ingrown hairs. Do not use Zeno for insect or spider bites or stings. Do not use Zeno for skin infections or for open sores or wounds because it may delay proper treatment or injure your skin.
- Do not use Zeno if your skin is sensitive to heat, sun or chemicals, because Zeno uses heat to treat pimples and the heat may damage your skin. Test your skin's reaction to Zeno's heat level by first testing Zeno on your forearm (see page 18).

Warnings

CONTACT your health care professional and stop using Zeno if you have an adverse reaction from using Zeno. If you do not get medical advice, your reaction may get worse. Consult your physician before using Zeno if you are also using any oral or topical antibiotic, or a product or medicine that may abrade or cause your skin to be sensitive to heat.

KEEP ZENO AND THE WALL CHARGING PLUG AWAY FROM WATER.

To reduce the risk of electrocution or product damage:

- DO NOT** place Zeno or the Wall Charging Plug where it can fall or be pulled into water. If Zeno is plugged in and falls into water or the Wall Charging Plug falls into water and you touch the water, this could result in serious injury or fatal electrical shock.

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- NEVER use Zeno when bathing or standing in water. If you and Zeno touch the water, this could result in serious injury or fatal electrical shock.
- NEVER use the Wall Charging Plug and cord if either is wet or if you think they may have been immersed in water. If you use the Wall Charging Plug when it is wet, this could result in serious injury or fatal electrical shock.
- DO NOT force the Wall Charging Plug into an outlet. The Wall Charging Plug is designed for use with specific electrical voltage; if it does not plug in easily, there may be a mismatch. You can damage the Wall Charging Plug or your electrical outlet. This could result in a serious injury or fatal electrical shock. Look at the Wall Charging Plug for voltage specifications or contact us.

To reduce the risk of burns or injury:

- DO NOT use Zeno on or around the eyes or lips. These very sensitive areas of the face may make the use of Zeno too painful. You may experience significant skin redness and swelling or even burns.
- If Zeno feels painful, discontinue use and contact Tyrell Customer Service in the U.S.A. at +1 281 880 6541.
- DO NOT use Zeno on blackheads, whiteheads, severe nodular acne or severe cystic acne. Zeno has not been tested on these types of acne. It is possible that the device may be ineffective or these types of acne may become worse upon use of the device.
- ALWAYS closely supervise the use of Zeno on or by children. Zeno is a medical device with specific instructions for use that may not be understood by children. Zeno may not be safe for use on young children with sensitive skin. Burns or injury may result.

- ALWAYS use with Zeno replacement Treatment Tip Cartridges recommended by Tyrell, Inc. You can buy replacement Treatment Tip Cartridges where you purchased Zeno. Tip cartridges not made by Tyrell may damage Zeno. Their use could result in burns or injury.
- NEVER operate the Wall Charging Plug if its cord or plug is damaged, if it is not working properly, or if it has been damaged in any way. Using a damaged Wall Charging Plug could result in serious injury or fatal electrical shock.
- ALWAYS keep Zeno and the Wall Charging Plug away from heated surfaces. High heat may damage the case or internal parts or both. Using a damaged Zeno or Wall Charging Plug could result in serious injury or fatal electrical shock.

Precautions

- ALWAYS clean the Treatment Tip before each treatment cycle. Cleaning the Treatment Tip before use helps avoid spreading germs. Germs can cause infections.
- DO NOT overuse Zeno. The Treatment Recommendations and What to Expect section directs treatment of an acne pimple for up to three treatments over 12 to 24 hours. Overuse of Zeno could result in burns or injury.
- DO NOT use Zeno if you think your blemish is worse after use of the device or if the blemish looks different than is described in this manual. If you are concerned about any change in your skin, contact your health care professional.

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In addition, some side effects not listed may occur. They usually do not require medical attention. If you notice any other side effects, check with your health care professional.

Care and Maintenance

- DO NOT leave Zeno in high heat, humidity, or direct sunlight.
- DO NOT open Zeno other than to remove the cap or replacement Treatment Tip Cartridge; any attempt to open may damage Zeno and will void the product warranty. The rechargeable batteries cannot be replaced.
- DO NOT drop or subject Zeno to strong bumps or knocks.
- DO NOT immerse Zeno in water. Immersion in water may result in product failure. To clean the Treatment Tip, wipe with a clean cloth and warm soapy water or alcohol. DO NOT use abrasives or chemicals. Water, abrasives, or chemicals can damage Zeno and may result in product failure.

- DO NOT leave Zeno in high heat, humidity, or direct sunlight. Doing so can damage Zeno and prevent it from working properly.
- DO NOT open Zeno other than to remove the cap or to replace the Treatment Tip Cartridge; any attempt to open may damage Zeno and will void the product warranty. The rechargeable batteries cannot be replaced. A risk of injury may result from opening Zeno.
- DO NOT drop or subject Zeno to strong bumps or knocks. Zeno is a precise medical device, and reduced product performance may result from damage to the device.
- DO NOT immerse Zeno in water. Immersion in water may result in product failure. To clean the Treatment Tip, wipe with a clean cloth and warm soapy water or alcohol. DO NOT use abrasives or chemicals. Water, abrasives or chemicals can damage Zeno and may result in product failure.

Risks and Benefits

You can trust Zeno for the treatment of individual acne pimples. Zeno is a handheld medical device that gives a precise heat dose to individual acne pimples. It quickly makes pimples fade or disappear with no major side effects.

Clinical trials reported no major side effects. However, some side effects which might occur are brief soreness due to heat, brief skin redness, or dryness or peeling of skin.

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Helpful Hints

- Before your first treatment, get used to the treatment by following Steps 1 through 4 detailed in the How to Use Zeno section on page 7, but placing Zeno on your forearm instead of on a pimple. You should not find the heat dose painful. In most cases the skin becomes less sensitive quickly. Press the Treatment Activation Button  again to stop the treatment. To avoid this test being counted as a treatment cycle, complete the test within 30 seconds.
- We suggest you use a mirror to properly place the Treatment Tip on a pimple and to make sure the tip remains in constant contact with the pimple during treatment. Be sure to PLACE, not PUSH, Zeno against the pimple. Extra pressure is not needed.
- The treatment cycle may be stopped at any time by pressing the Treatment Activation Button . If the cycle is stopped within the first 30 seconds, it will not be counted as a treatment and will not reduce the total treatment count.
- As a safety feature, Zeno allows only 3 treatment cycles in succession. If you attempt to go over this limit, Zeno will employ a Safety Delay Feature. You may begin more treatments after 2 minutes.
- Please note that facial hair may prevent full and complete contact with the pimple. It is important to have full and constant contact with the pimple during the treatment cycle.
- If your skin is light, you may be more likely to have redness around the treatment area. In almost all cases, such redness is normal and should not cause alarm. If you experience an adverse reaction, stop using Zeno and contact your health care professional.

Troubleshooting

When I press the Power Button , nothing happens.

Make sure that Zeno is fully charged (charge for 6 hours if the battery has no charge left); look at the Battery Charge Indicator  to be sure. Plug Zeno into an electrical outlet using the Wall Charging Plug  to be sure electrical power is reaching Zeno. The Battery Charging Indicator will flash. For safety reasons, Zeno will not work while plugged into the Wall Charging Plug.

About 30 seconds after starting a treatment cycle, I hear multiple beeps and the Treatment Activation Button glows amber.

You have forgotten to start a treatment cycle by pushing the flashing green Treatment Activation Button .

When I press the Power Button , the Treatment Activation Button  glows amber; but after waiting at least 2 minutes, the Treatment Activation Button  does not flash green and/or I hear the Attention sound.

Make sure a Treatment Tip Cartridge  is installed. (See Replacing the Treatment Tip Cartridge section.)

Make sure that there is at least one treatment cycle left in the installed Treatment Tip Cartridge  (look at the Treatment Tip Life Indicators ). (See Treatment Tip Life Indicators section.)

Make sure that the battery is charged (look at the Battery Charge Indicator ). (See Charging Your Zeno's Batteries section.)

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When I press the Power Button , the Treatment Activation Button  glows amber, but then Zeno powers off and I hear the Power Off sound.

Make sure that the battery is charged (look at the Battery Charge Indicator ).

Make sure that a Treatment Tip Cartridge  is installed.

Make sure that you have not pressed the Power Button  again by mistake.

If Zeno's computer detects that Zeno is not at its correct ready status within 180 seconds, it will power itself off. If this happens, contact Tyrell Customer Service in the U.S.A. at +1 281 880 6541 or at www.myzeno.com.

My battery will no longer fully charge; can I still use the unit?

No. Although your Zeno is designed for years of service (about 3 to 4 years under normal use), the batteries in Zeno cannot be replaced. For safety reasons, Zeno will not work while plugged into the Wall Charging Plug . (See Disposal section.)

Following a treatment cycle, I want to treat another pimple, but the Treatment Activation Button  does not flash green, I do not hear the Ready sound, and/or I hear the Attention sound.

Make sure you have waited the required 10 seconds between treatment cycles.

Make sure that you have not tried to use more than 3 treatment cycles in succession. (Note the Safety Delay Feature described in the Helpful Hints section.)

Make sure that the battery is charged (look at the Battery Charge Indicator ).

Make sure that at least one treatment cycle is left (look at the Treatment Tip Life Indicators ).

After a treatment cycle, I hear multiple beeps and the Treatment Activation Button  glows amber.

Zeno has counted 3 treatment cycles in succession and has started the 2-minute Safety Feature hold period. When this hold period is over, you will hear the Ready sound and the Treatment Activation Button  will flash green.

After a treatment cycle, Zeno powers off and I hear the Power Off sound.

Make sure that the Treatment Tip Cartridge  has not been removed.

Make sure that the battery is charged (look at the Battery Charge Indicator ).

Make sure that you have not pressed the Power Button  by mistake.

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Use Outside the United States

Zeno's Wall Charging Plug is designed for use with either an electrical input of 120V at 60 cycles or 100-240V at 50/60 cycles. Please check the label on the Wall Charging Plug to match the local electrical input before use. Do not use with any other electrical service. Check local electrical service when traveling outside the United States.

Storage

Always keep Zeno in a dry place and avoid extreme temperatures. Keep Zeno away from heat, humidity, direct sunlight or harmful chemicals.

Disposal

Do not crush, burn or open the Zeno case. Zeno should be disposed of in accordance with all current country regulations. Zeno replacement Treatment Tip Cartridges may be thrown away with normal garbage.

The Zeno Money-Back Guarantee

If you're not completely satisfied that Zeno makes your pimples go away fast, we'll refund your money. Simply return your Zeno within 30 days of original purchase. Zeno must be returned in the original packaging, along with all package contents and your original store sales receipt.

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Limited One-Year Warranty

Register your purchase of Zeno at www.myzeno.com. Your Zeno is warranted to be free from defect in material and workmanship for a period of one year under normal use after its original purchase date. This warranty extends only to the original retail purchaser and only when purchased from an authorized Zeno retailer.

If the product should become defective within the warranty period, contact Tyrell, Inc. Customer Service in the U.S.A. at 1-281-380-6541 for repair or replacement. Tyrell reserves the right to replace a defective product with the most comparable product currently available.

This warranty does not cover products damaged by the following:

- Accident, misuse, abuse or alteration
- Servicing by unauthorized persons
- Use with unauthorized accessories
- Connecting to incorrect current and voltage
- Any other conditions beyond our control

TYRELL, INC. SHALL NOT BE RESPONSIBLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OF THIS PRODUCT. ALL IMPLIED WARRANTIES INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF FITNESS AND MERCHANTABILITY ARE LIMITED IN DURATION TO ONE YEAR FROM DATE OF ORIGINAL PURCHASE.

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, or limitation on how long an implied warranty lasts, so this disclaimer may not apply to you.

ZENO

Quick Start Guide

- 1 Make sure battery is fully charged
- 2 Clean tip
- 3 Press 
- 4 Press  when flashing green
- 5 Place on pimple
- 6 Listen for Treatment Pacer tone every 30 seconds
- 7 Remove after Treatment Complete tone (2½ minutes,  turns amber)

For additional pimples, repeat steps 4 through 7

If needed, re-treat again after 4 to 12 hours

Tip Life

- ● ● ● 68 to 90 treatments
- ● ● ○ 46 to 67 treatments
- ● ○ ○ 23 to 45 treatments
- ○ ○ ○ less than 23 treatments
- ☀ ○ ○ ○ 5 or fewer treatments
- ☀ ☀ ☀ ☀ Replace

Battery Life

- Adequate to full
- ☀ Recharge soon
- Must recharge

See warnings on reverse

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Read Product Manual

To reduce the risk of electrocution or product damage, keep Zeno and the Wall Charging Plug away from water.

DO NOT place Zeno or the Wall Charger where it may fall/be pulled into water or around heated surfaces.

DO NOT use Zeno if the Treatment Activation Button is illuminated amber.

DO NOT use Zeno until the Treatment Activation Button flashes green.

DO NOT reach for Zeno if it is plugged into an outlet and falls into water. Unplug before retrieving from water.

DO NOT use Zeno when bathing, standing in water, or on and around the eyes and lips.

DO NOT force the Wall Charger Plug into an outlet or operate if its cord/plug is damaged, or if it is not working properly.

DO supervise children while they use Zeno.

DO use Zeno only for the purposes described in the Product Manual and only use Zeno Replacement Tip Cartridges.

Should you experience any discomfort when using Zeno, discontinue use and consult your skin care professional.

Failure to comply with all warnings could result in a serious injury or fatal electrical shock.

Manufactured for Tyrell, Inc. Houston, TX 77067
888-4MY-ZENO or 888-469-9366
www.myzeno.com Label No. 01, 05/05



ZENO

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» [Product & Science Literature / Clinical Trials](#)

Home : [Clearpoint Technology](#)



ClearPoint Technology

Groundbreaking technology at your fingertips!

ClearPoint technology is the key to Tyrell's ability to provide heat therapy for the successful treatment of skin lesions.

Tyrell's proprietary ClearPoint™ technology delivers a precisely controlled heat dose for a specific period of time to a pimple. This heat triggers a cascade of events that include the induction of heat shock protein responses and the subsequent killing of the bacteria. This effectively reduces the inflammatory response and allows the skin to return to a healthy state more quickly.

[Heat Treatment of Acne Lesions](#)

[Clinical trial evidence for effectiveness of heat treatment](#)



Retake control of your skin!

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Home : Clearpoint Technology : The Science of Heat

The Science of Heat

The science of heat applied to acne.

With Tyrell's ClearPoint™ acne heat treatment technology, *P. acnes* is destroyed by a process called heat shock response. Heat shock response is a reaction bacteria have to heat whereby they transcribe a number of their genes and activate heat-shock proteins. These heat-shock proteins participate in the bacteria's death by causing the bacteria to self-destruct. *P. acnes* self-destructs in the acne lesion preventing infection and allowing the skin to return to a healthy state. Fortunately, the level of heat required is not sufficient to cause damage to the skin.

Tyrell performed numerous lab studies on *P. acnes* to assess the temperature range in which heat shock response occurs in this bacteria, including a waterbath and a thermal cycler study, known for accuracy to tenths of a degree. DNAtrix, Inc., a molecular pharmaceutical company jointly owned by Dr. Conrad and the Board of Regents of the University of Texas, performed the thermal cycler testing which was critical in determining if *P. acnes*' heat shock response occurs below the point of heat damage of human skin. Furthermore, these tests were critical in assessing the rate of *P. acnes* death at various temperatures over time (temperature versus time). The results indicated significant death of *P. acnes* at a temperature well below the thermic damage of human skin.



Treats pimples better than any product available without a prescription!

Purchase Zeno Now!

How Zeno Works



Before



After

Zeno skin treatment is proven effective in treatment of adult acne.

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ZENO

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Zeno

Introducing Zeno, the new secret weapon in the war against acne.

Zeno Acne Treatment

Clinically proven portable, hand-held rechargeable medical device for at-home treatment of individual acne inflammatory pimples.

Zeno is an acne clearing device. It is a hand-held, portable electronic medical device that is clinically proven to make pimples disappear fast. In fact, for treating **acne pimples**, it's the most scientifically advanced and effective device available without a prescription. Zeno is for people with mild to moderate inflammatory acne.

Clear up your acne. Eliminate your pimples with the Zeno.

Clinically proven portable, hand-held rechargeable medical device for at-home treatment of individual inflammatory acne pimples.

Effective Acne Treatment

Zeno clears pimples in people with mild to moderate inflammatory acne. It is a hand-held, portable electronic medical device that is clinically proven to make pimples disappear fast. Zeno is the most scientifically advanced and effective acne device available without a prescription.

The proprietary Zeno technology triggers a heat shock response in microorganisms that cause skin lesions, bringing about the self-destruction of those bacteria and allowing the skin to return to a healthy, normal state. In the case of acne, the *P. acnes* bacterium is the root cause of 90% of all acne pimples.

Zeno™ is a simple electronic product designed to safely heat an acne lesion to a pre-set temperature range known to generate heat shock response. Heat shock response is a reaction bacteria have to heat whereby they transcribe a number of genes and activate heat-shock proteins. These heat-shock proteins participate in the bacteria's death by causing the bacteria to self-destruct.

Zeno Treatment

Pimples occur when excess skin oil and flaking skin plug the opening of a hair follicle and create the ideal environment for acne bacteria to grow. Precisely controlled heat applied for a specific period of time causes the bacteria to self-destruct. When the bacteria die, the pimple goes away.

Zeno applies a precisely controlled heat dose directly to the pimple through a metal pad. [Learn about thermal treatment of acne pimples.](#) [Learn about acne and pimples.](#)

Safe, painless, and effective acne treatment

Zeno can clear up a pimple in just hours. Two to three 2½-minute treatments spread over 24 hours are sufficient for most pimples. Often, only one treatment is needed. Most other medications can take days or even weeks to work.

Patients included in our clinical trials experienced little reaction to the low-level heat. Other than some temporary skin redness following a treatment cycle, no other adverse side effects were reported.



Treats pimples better than any product available without a prescription!

Purchase Zeno Now!

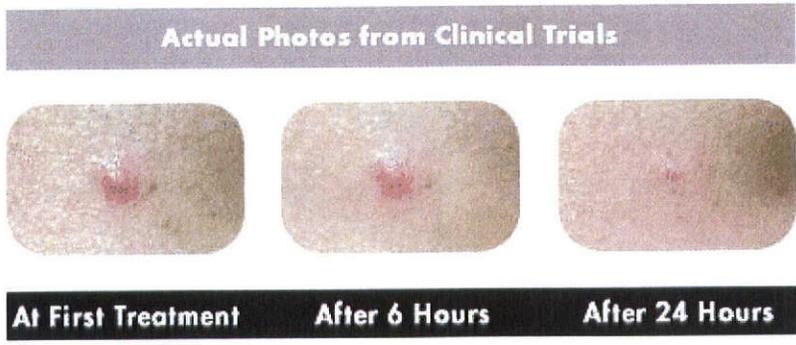
FAQ's

How Zeno Works

 Warranty Info

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Records processed under FOIA Request # 2013-5590; Released by CDRH on 8/6/2015



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Significant Efficacy and Safety of Low Level Intermittent Heat in Patients with Mild to Moderate Acne

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¹Suzanne Bruce and Associates, ²Tyrell Inc., ³Synergos Inc.

Abstract

Patients with mild to moderate acne that do not require prescription medications are limited to over the counter (OTC) preparations. Unfortunately, many of these preparations are of limited value. We investigated and demonstrated that the application of low to moderate levels of sustained heat was effective in reducing colony counts of *P. acnes* bacteria in pre-clinical studies. This suggested that the application of low-level sustained heat could potentially be beneficial to individual acne lesions. A small hand-held device was constructed that allowed the delivery of a thermal dose of 121° F (49.4° C) for 2.5 min and a surface area of roughly 0.099 in². This device was used to evaluate this particular technique in a placebo controlled double-blind clinical trial. Patients (51) were enrolled in this trial, all of which met the protocol inclusion criteria and had mild to moderate acne and were not currently on systemic medications. The results demonstrated that the active treatment significantly shortened both the median time to improvement (12.8 versus 35.6 hours, $p < 0.0001$, Log-Rank test) as well as the median time to resolution (89.7 versus 140.1 hours, $p = 0.0020$, Log-Rank test) as reported by the subjects. The observations were made by blinded physicians and by subjective analysis by the patients undergoing this treatment. These objective and subjective evaluations had a high level of agreement, suggesting both internal consistency with both the treatment as well as the clinical design. Additionally, this treatment modality was without any adverse events either observed by the monitoring physicians or by the subjective diaries submitted by the treated subjects. These results suggest that this treatment is both effective and safe for patients that experience mild to moderate acne.

Background

Acne is a chronic inflammatory disorder of the pilosebaceous unit that has been associated with *Propionibacterium acnes* (*P. acnes*) and is

estimated to affect approximately 85% of adolescents and young adults.^[1, 2] Patients who suffer from mild to moderate acne are generally treated with over the counter (OTC) topical cleansers, astringents and benzoyl peroxide preparations with occasional prescription of topical or systemic antibiotics provided when more severe flares occur. These OTC preparations are minimally effective and patients that fall into this category often feel the psychological pain of few effective treatments and of chronic persistence of this disease process.^[3, 4] Moreover, most of these patients do not qualify for more drastic treatment with agents such as *cis-retinoic acid* (Accutane). In addition, due to more stringent requirements placed on physicians able to prescribe Accutane, fewer patients are being offered this treatment modality. It is also becoming increasingly clear that *P. acnes* is developing increased resistance to antibiotics treatments making this modality less effective and desirable.^[5] The longstanding recognition that hot compresses can be very effective in the treatment of some small localized abscess formations^[6], prompted us to evaluate if low level heat could be effective in the treatment of *P. acnes* and therefore possibly acne lesions.

Although it is not precisely clear how the normal colonization within a hair follicle of *P. acnes* triggers the inflammatory reaction pathogenic of an acne lesion, most researchers agree that these bacteria are at least partially if not fully responsible in the pathophysiology triggering acne lesions.^[7] It was this rationale and the recognized emergence of antibiotic resistant strains of *P. acnes* that lead us to investigate the possibility of targeting these bacteria by an alternate method to control it, namely heat. We postulated that if *P. acnes* could be eliminated or reduced within a forming acne lesion, then this treatment may promote quicker resolution of this process.

We first evaluated the heat responses of *P. acnes* anaerobic cultures to various heat ranges and a variety of exposure times to determine if tolerable heat levels and exposure times could be found that kill the bacteria but would at the same time be

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tolerable to patient's skin. These investigations were followed by producing a prototype device, which can maintain heat to a small treatment tip in a very controlled and accurate fashion. The device was then tested on the investigators to subjectively determine which heat ranges were tolerable. Interestingly, the heat ranges found to be tolerable and seemingly safe were in the range that was able to reduce colony counts from treated *P. acnes* anaerobic cultures. Finally, the chosen temperature level, exposure time and treatment frequency were tested in a double-blind placebo controlled clinical trial. Results of this trial are reported here and demonstrate significant clinical efficacy without any adverse reaction.

We have experience in determining the survival of the bacterium *P. acnes* when exposed to various heat sources and to various lengths of time. This information is critical in determining the heat tolerance of human tissue versus the tolerability of *P. acnes* under thermal delivery. Based on research to evaluate these parameters, we have been able to endow Zeno™ with optimal heat and timing characteristics to effectively treat the underlying cause of acne and pustular-form eruptions through localized thermal delivery.

Materials and Methods

Cultures

The bacterial strain *P. acnes* was purchased from The American Type Culture Collection ATCC (No. 11827, Lot 419571, Manassas, VA). The cultures were stored in KWIK-STIK lyophilized preparations.

***In Vitro* Procedures**

The lyophilized cells (*P. acnes*) were rehydrated according to the manufacturer's recommendations and initially grown on a streak plate to isolate individual colonies under anaerobic conditions and with sterile phosphate-buffered saline and then streaked using sterile technique with a wire loop on to TSA-plates. These plates were then incubated overnight at 37° C in an anaerobic chamber. Individual colonies were then isolated and inoculated into TSB-growth media with medium agitation overnight. From these aliquots of 0.1 ml of TSB, broth culture was added to the 0.9 ml of PBS sterile buffer. This mixture was then transferred to thin-walled Eppendorf 1.5 ml tubes and placed in a heating block at various times and temperatures. The cultures, after specific incubation times, were removed and 0.1 ml of the material was plated onto TSA plates. This mixture

was then spread with a sterile hockey-stick and then allowed to incubate at 37° for five (5) days in anaerobic conditions. The plates were then removed and colonies were counted and recorded.

Prototype Device

The specific engineering details of the device construction are beyond the scope of this manuscript. Essentially the device was designed and constructed to maintain a precisely controlled temperature at a treatment tip size of approximately 3/8 inch in diameter. This was accomplished through regulating the power applied to a heating element using a closed loop feedback system. The device used Proportional, Integral and Differential (PID) calculations in determining the necessary power applied to the heating element to quickly ramp the temperature to the set point, while minimizing any overshoot effects of the target temperature. The PID system was also used to maintain temperature regulation of the device treatment tip to within 1° C from the set point, thereby allowing a constant precise temperature to be applied to the lesion throughout the treatment cycle.

Clinical Trial

The clinical trial was designed as a double-blind placebo-controlled study that enrolled patients with mild to moderate acne and who were not receiving concurrent prescription medications.

This randomized double-blind study was controlled within each subject. Subjects received treatments with both active and placebo devices. After a subject had been determined to meet the eligibility criteria and had signed Informed Consent, two (2) similar, clinically-matched single blemishes were selected for treatment, one (1) with the Zeno device and one (1) with the placebo device. The placebo device was identical in appearance to the Zeno device but did not deliver any heat. An unblinded administrator administered treatments with active and placebo devices in an identical fashion. Neither the subject nor the Physician performing the study related assessments knew to which treatment assignment each blemish was assigned.

Blinding

At each site initiation, a randomization list was provided to the unblinded study staff. This list designated which treatment, active or placebo, each blemish was to receive. The Investigator instructed the study staff where the selected

blemishes were located on the face. Both study blemishes to be treated were photographed and labeled as "Blemish 1" or "Blemish 2", along with the date the photographs were taken, to ensure that the additional treatment administrations and assessments of the treated areas would be associated with the correct acne blemish and treatment. Each subject received three (3) study treatments to each blemish of 2.5 minutes each. The two (2) treatments on Day 1 were to be a minimum of at least one (1) hour and no longer than 12 hours apart. The third treatment was performed on the second day and occurred at a minimum of 18 hours and no later than 48 hours after the first treatment. Subjects had photographs of the actively treated and placebo treated blemishes taken for documentation purposes. Investigator evaluation of the actively treated and placebo treated blemishes was conducted prior to treatment on Days 1 and 2 and at the Day 5 follow-up visit. Subjects assessed their blemishes using a Subject Diary and VAS tenderness scale twice daily (am/pm) until resolution of both blemishes or Day 14, whichever occurred earliest.

Sample Size

The study was planned for a total of 50 subjects. Each subject was required to have had two (2) similar blemishes treated and assessed, one (1) treated with the Zeno (active) device and one (1) treated with a placebo device. The sample size was based on safety considerations and the probability of experiencing adverse events. A sample of 50 allowed adequate power to detect the incidence of rare safety events. A sample of 50 subjects yielded 95% probability that the study would reveal at least one (1) occurrence of all events that occur at a rate of 5.8% or greater. This sample size was adequate to demonstrate that the Zeno device was safe and effective.

Statistical Considerations

Standard statistical methods were employed to analyze all data. The following techniques were used: descriptive statistics, paired t-test, Fisher's Exact test, Kaplan-Meier techniques, McNemar's test, Bowker's test and graphical displays. Assumptions of normality and homogeneity of variance were tested with the Shapiro-Wilks test. If the distributional assumptions were violated, non-parametric techniques, such as Wilcoxon's rank-sum test were employed. All tests were declared statistically significant if the calculated p-value was less than or equal to 0.0500. All tests appeared as two-sided p-values.

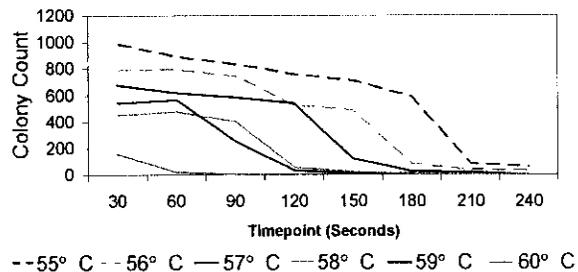
Summary statistics consisted of numbers and percentages of responses in each category for discrete measures, and of means, medians, standard deviations, 95% confidence intervals, minimum, and maximum values for continuous measures, and are presented for each treatment group, where applicable. Version 8.0 or higher of the SAS® statistical software package was used to provide all statistical analyses.

Results

Pre-clinical

The temperature kill assay performed clearly demonstrated that *P. acnes* is sensitive to increasing temperatures. There was a general trend of reduction of the required time needed to reduce the colony counts at higher temperature incubations. **Figure 1** demonstrates the rapid decline of *P. acnes* in response to various temperatures and duration of treatment. Also of note is what appears to be a temporal thermal threshold, whereas the number of viable colonies drops off in a very steep fashion. By using the curves generated by such experiments the optimal thermal output and the timing for each temperature can be extrapolated for a localized heating device. For some of the higher temperatures, or very long periods of time the number of colonies drops off below the detection

Figure 1. Temperature Death Curves for *P. acnes*

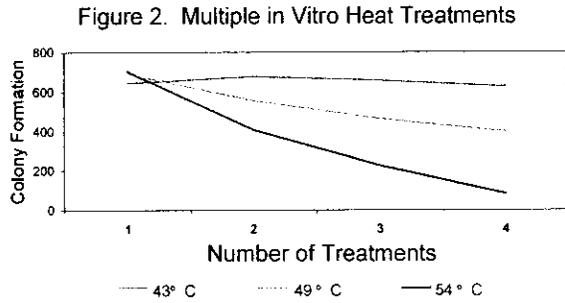


limits of this particular dilution assay. It should be noted that probable longer drop-offs are seen and multiple serial dilutions may be useful to further define the extent of these curves at the higher temperatures and longer incubation times.

Next, the effects of multiple treatments were then investigated. Cultures were established as before, however the treatment with heat was repeated for four (4) time points on separate occasions to evaluate if there was an additive effect. **Figure 2** demonstrates a clear difference in the viability of *P. acnes* colony formation with increasing number

of treatments provided. The data shown represent four (4) treatments given to the individual cultures. These results suggest strongly that pulsing treatment can be very effective in reducing colony counts of *P. acnes*.

In summary, the in vitro data shown demonstrates significant sensitivity of *P. acnes* bacterial cells to the effects of sustained low-level heat as well as pulsing heat treatments, these treatments provide



the conceptual basis for the localized treatment with this modality. Due to these results, a clinical trial was initiated to confirm that this treatment strategy is able to translate into effective in vivo treatment.

Clinical trial results

Efficacy Results

There were fifty-one (51) patients enrolled in this study. The patient demographics are given in **Table 1** and represent a slight female to male predominance (30 versus 21) and a median age of 20.0. Zeno treated blemishes resolved faster than placebo treated blemishes. The differences in time

Table 1. Demographic Information	
Attribute	Mean ± SD or N (%) (N=51)
Age (years)	20.0 ± 6.3
Gender	
Male	21 (41.2%)
Female	30 (58.8%)
Ethnicity	
White	33 (64.7%)
Black or African American	12 (23.5%)
Hispanic or Latino	4 (7.8%)
Asian	1 (2.0%)
Persian (Asian)	1 (2.0%)

to improvement between active and placebo treatments are easily seen by graphing the time to improvement and/or resolution of lesions by Kaplan-Meier curves (**Figures 3 and 4**). In

Figure 3. Hours to Resolution in the Subject Diary

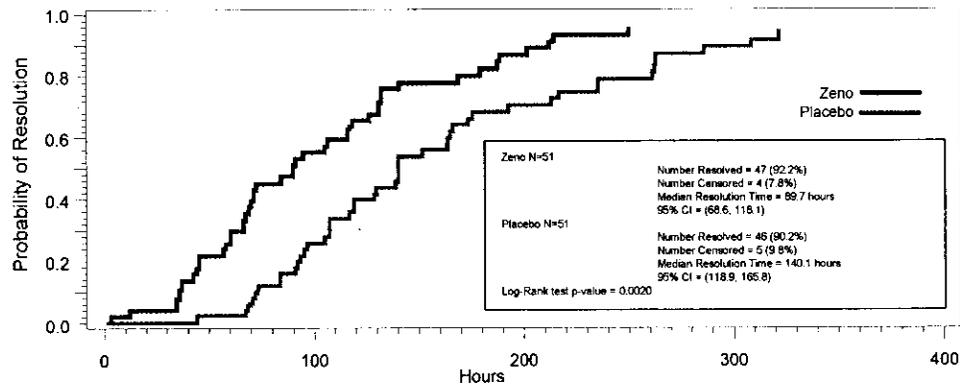
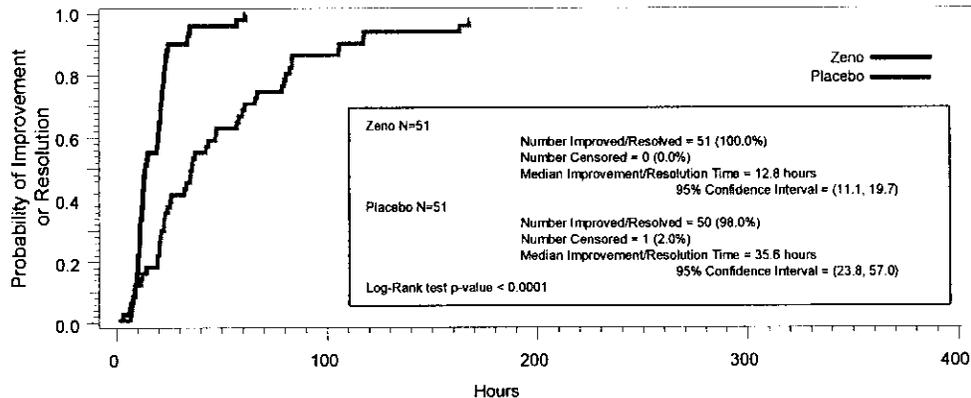


Figure 4. Hours to Improvement or Resolution as Reported in the Subject Diary



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instances where blemishes were not fully resolved within 14 days, the data was censored.

The median resolution time for the blemishes treated with the Zeno device was 96.7 hours,

Time	Zeno (N=47) Mean ± SD	Placebo (N=46) Mean ± SD	Paired Difference* (N=46) Mean ± SD
Days	3.9 ± 2.5	6.3 ± 3.0	2.3 ± 2.8
Hours	96.7 ± 58.5	151.8 ± 71.5	53.7 ± 65.6

* N corresponds with the Number of Blemishes Resolved
* Paired difference was calculated as Zeno subtracted from Placebo, thus a positive difference indicates that the Zeno treated blemish resolved faster than the Placebo treated blemish.

compared to 151.8 hours for the blemishes treated with the placebo device (Table 2), which is a statistically significant difference (p-value = 0.0001, Log-Rank test). Blemishes treated with the Zeno device also showed improvement sooner than placebo treated blemishes. The median time to resolution or improvement for the blemishes treated with the Zeno device was 12.8 hours,

Treatment	Blemishes Resolved (%)	Blemishes Censored (%)	Median Resolution Time (Hours) (95% CI)	Log-Rank p-value
Zeno (N=51)	47 (92.2%)	4 (7.8%)	89.7 (68.6, 118.1)	< 0.0001
Placebo (N=51)	46 (90.2%)	5 (9.8%)	140.1 (118.9, 165.8)	

Time	Zeno (N=51) Mean ± SD	Placebo (N=50) Mean ± SD	Difference* (N=50) Mean ± SD
Days	0.5 ± 0.6	1.8 ± 1.7	1.3 ± 1.6
Hours	17.2 ± 11.2	48.0 ± 39.1	30.8 ± 36.5

* N corresponds with the Number of Blemishes Resolved
* Difference was calculated as Zeno subtracted from Placebo, thus a positive difference indicates that the Zeno treated blemish resolved faster than the Placebo treated blemish.

compared to 35.6 hours (Table 3 and 4) for the blemishes treated with the placebo device, also a statistically significant difference (p-value < 0.0001, Log-Rank test). Also shown are composite

bar graphs (light color showing lesion improvement and dark color showing lesion resolution) that are based on the blinded Investigator's evaluation in Figure 5 and subjects' evaluations as reported in the daily diary in Figure 6. As shown in Figure 5, 29.4% of the Zeno treated blemishes resolved or improved with only

Figure 5. Percentage of Blemishes Resolved or Improved as Reported by the Investigator

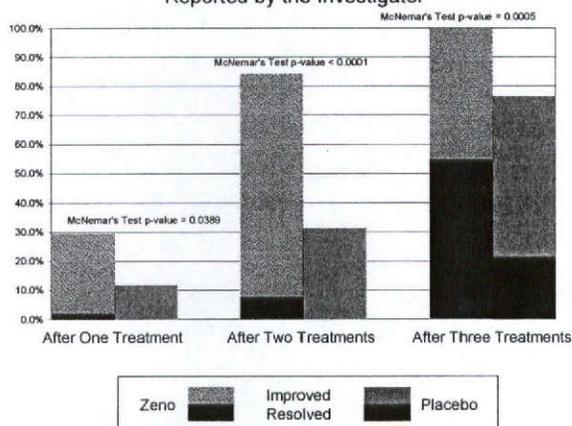
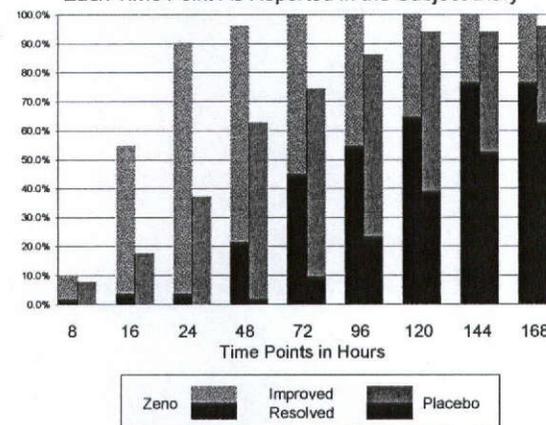


Figure 6. Percentage of Blemishes Resolved or Improved at Each Time Point As Reported in the Subject Diary



one (1) treatment versus 11.8% of the placebo treated blemishes. With only two (2) treatments, 84.3% of Zeno treated blemishes resolved or improved versus 31.4% of the placebo treated blemishes. At the Day 5 follow-up, 100.0% of the Zeno treated blemishes resolved or improved compared to only 76.5% of the placebo treated blemishes. The proportion of blemishes that resolved or improved was statistically significant at each of these time points (each p-value < 0.05, McNemar's test). A panel of photographs (Figure 7 and Figure 8) is also shown to demonstrate the

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Figure 7. Patient Study Photographs

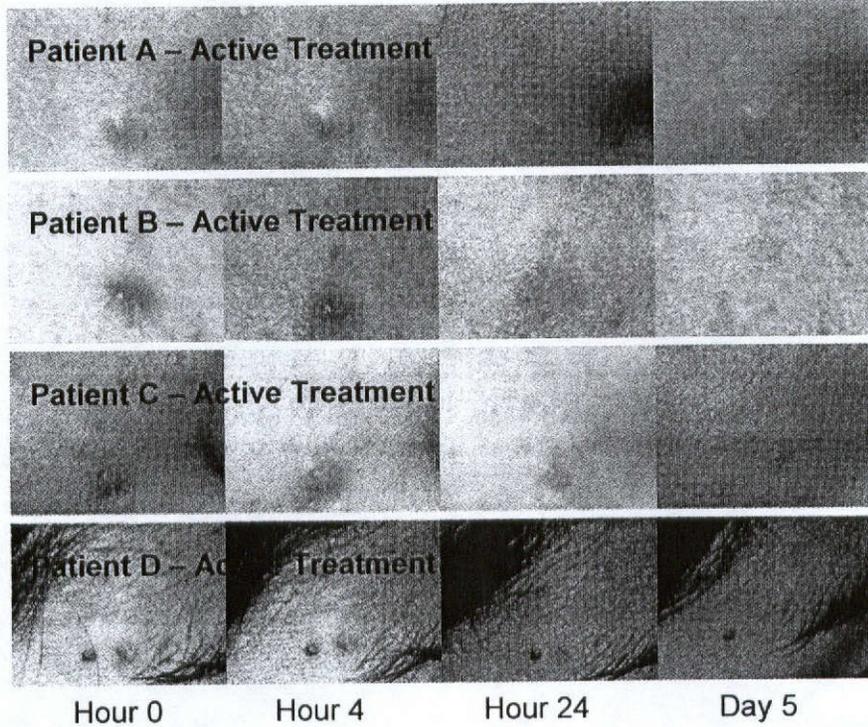
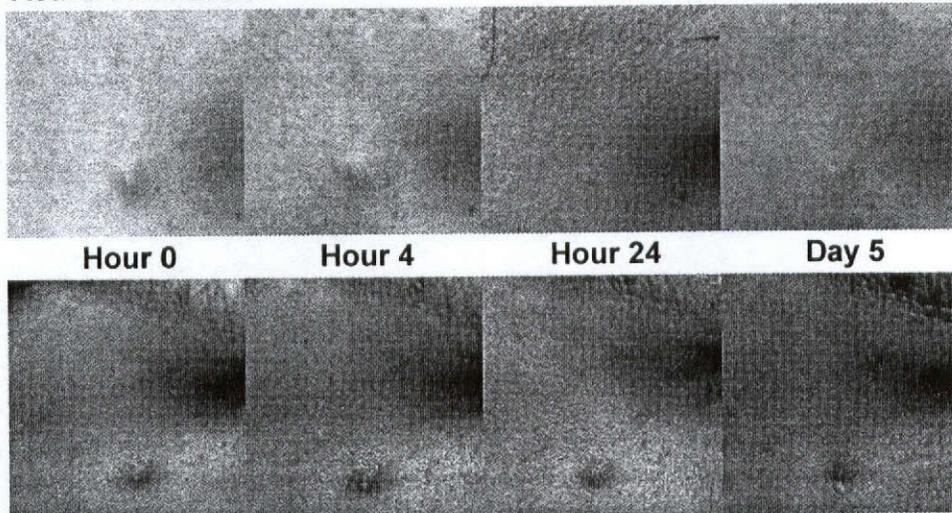


Figure 8. Patient A Comparison of Active and Placebo Treatments



Placebo Treatment

effect on four (4) of the subjects during the treatments.

All of the analyses of the blinded Investigator blemish assessments and subject diary blemish

assessments support that the Zeno treated blemishes improve and resolve faster than the clinically matched placebo treated blemishes.

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Safety Results

Subjects did not experience any adverse events or serious adverse events for the duration of this study, monitored from the time of the first treatment with study device through Day 5. There were no device complications reported during this study. Both questions from the investigators as well as subjective evaluations provided by the individual diaries are in complete agreement with each other, specifically no adverse events were reported.

Discussion

Provided herein is an alternative to currently available strategies to treat mild to moderate acne outbursts in patients with a simple handheld device that delivers a very controlled temperature at predefined times.

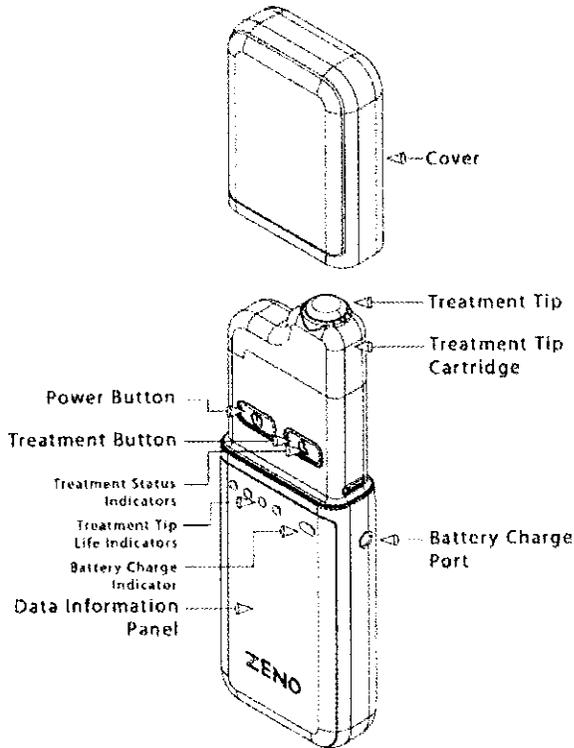
The Zeno device (shown in **Figure 9**) was evaluated in a double-blinded controlled clinical trial and demonstrated significant improvement in the resolution time of individual acne lesions from active versus placebo devices. Both objective and subjective measures of lesion improvement or

resolution were significantly observed in both hours and days. Importantly, there were no adverse reactions to this treatment nor were there any complications with the device.

Although, *P. acnes* is quite sensitive to heat treatments, the exact mechanism that triggers this death response is not clearly defined. It is well known that various "heat-shock" proteins increase in cells after exposure to stress events as well as heat.^[8-12] These "heat-shock" proteins are increased and the cells then follow a well ordered death cascade. It is unclear whether these responses are causative in the death occurring after exposure to heat or whether these are merely adaptive responses that were ineffective in preventing the bacterial cell death. It suffices that these molecular changes are associated with bacterial cell death after heat treatment is applied.

This treatment modality is simple, non-toxic and effective against individual acne lesions and represents an additional tool for patients who suffer from mild to moderate outbreaks of acne.

Figure 9. Zeno Device



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Legends

Figure 1. This represents the reduction in colony counts of *P. acnes* after subjected to temperature at varying time points. The temperatures were given in Celsius from 55° up to 60° for various points of time at 30 second intervals. As can be seen there appears to be a time and temperature dependant threshold where the number of colonies can not be accurately counted at this particular dilutional scheme.

Figure 2. This represents the number of colony counts obtained at the three different temperatures of 43° C, 49° C and 54° C with multiple (4) X 2 ½ minute treatments being applied. The number of treatments is seen on the X-axis up to four 2 ½ minute treatments. As can be seen, the number of treatments at various temperature profiles significantly reduces the colony count and viability.

Figure 3. Represents a Kaplan-Meier curve showing the time to resolution as recorded in the subject diary for both the active treatment and placebo treatment. The number of patients resolved with the active treatment is 47 (92%) with the number of censored cases at 4 (7.8%) with a median time of resolution of 89.7 hours. For the placebo group, 46% report resolved (90.2%) with the number of censored cases being 5 (9.8%) with a median resolution time of 140.1 hours.

Figure 4. Represents the time to either improvement or resolution of the lesions as reported in the subject diaries as represented by Kaplan-Meier curves. The number of subjects that reported improved or resolved lesions with the active treatment was 51 (100%). The number of patients reporting improvement or resolution with the placebo was 50 (98%). Median time of resolution or improvement for the active treatment arm was 12.8 hours whereas the median time for improvement or resolution for the placebo group was 35.6 hours.

Figure 5. Represents the percentage of lesions either improved or resolved after either one treatment, two treatments or at 5 day follow-up evaluation. The light colors represent the portion of lesions that had improved and the dark colors represent the portion of lesions that had resolved for either the active treatment or the placebo treatment.

Figure 6. Represents the percentage of lesions either improved or resolved at each observation time point as reported in the subject diaries. Again, the lighter colors represent the portion of lesions that had improved and the dark colors represent the portion that had resolved for both the active treatment and placebo groups.

Figure 7. Photographs of actual patients (4) within the clinical trial demonstrating the improvement of lesions from base line at 4 hours, 24 hours and at day 5.

Table 1. Shows the demographic features of the patients involved in the study. The median age was 20.0 years. There was a female predominance of 58.8% compared to males at 41.2%. The table also shows a mix of ethnicities with a Caucasian predominance.

Table 2. Represents the median time for resolution between the active treatment, placebo treatment and the difference between the mean resolution time given in both days and hours. These results gave a significant p-value of less than 0.0001 in paired T tests.

Table 3. Represents the time to improvement or to resolution as reported in the subject diaries and given in hours. The median time in hours for either improvement or resolution was 12.8 hours for the active treatment group as compared to 35.6 hours for the placebo group.

Table 4. Represents the time to improvement or resolution for those blemishes that did improve in the subject diary for the active and placebo treatments and the difference as reported in days and hours. The median difference in hours between the two treatment groups was 1.3 days and 30.8 hours, respectively.

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ThermaClear™ Traditional 510K Document

K060653

OC1 2 4 2006

5. 510(k) Summary

DermaCare, Incorporated – ThermaClear™ Device

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

Owner's Name and Address: DermaCare, Inc.
6248 Preston Avenue
Livermore, CA 94551
(925) 371-3900 – Telephone
(925) 371-3903 – Fax

Contact Information: Heidi Stark
DermaCare, Inc.
6248 Preston Avenue
Livermore, CA 94551
(925) 371-3900 – Telephone
(925) 371-3903 – Fax

Date Prepared: March 2, 2006

Device Trade Name: ThermaClear™

Common Name: Acne Treatment Device

Classification Name: Class II - Laser instrument, surgical,
powered (21 CFR 878.4810, Product Code
GEX)

Predicate Devices: Tyrell, Inc.
Zeno
K043377

Radiancy (Israel) Ltd.
Radiancy Acne System With ClearTouch™
K032205

Description of the Device:

ThermaClear™ is a portable hand-held device that uses a short thermal pulse to treat mild to moderate inflammatory acne. The treatment tip is comprised of biocompatible

ThermaClear™ Traditional 510K Document

material and delivers a short duration thermal pulse that heats the area being treated. The device is powered by two AA alkaline batteries.

Indications for Use:

ThermaClear™ is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Performance Data:

Non-clinical and clinical performance testing was conducted with the ThermaClear™ device.

Preclinical Testing

ThermaClear™ was tested for EMI in accordance with the IEC 60601-1 standard. ThermaClear™ operates within the EMI emission, susceptibility and static discharge levels specified in the IEC 60601-1 standard.

Clinical Testing

Clinical testing was conducted in both a controlled practitioner office environment and a consumer home-use environment and submitted as part of the 510(k) application to confirm that ThermaClear™ is as safe and effective as the predicate device. The controlled clinical study design was a randomized, blinded study.

Substantial Equivalence:

ThermaClear™ and its predicate devices are all devices that use either heat or light to treat the dermatological condition of mild to moderate acne by exposing the surface of the skin to a precise energy fluence. The delivered energy heats the skin to accelerate resolution of the acne lesion with no risk of burns. The minor differences in the technological characteristics of ThermaClear™ and its predicate devices do not raise any new issues of safety or efficacy. Thus, ThermaClear™ is substantially equivalent to the predicate device for treatment of mild to moderate acne.

Conclusion:

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the proposed device has been shown to be safe and effective for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DermaCare, Inc.
% Mr. Peter Scocimara
CEO/President
6248 Preston Avenue
Livermore, California 94551

OCT 24 2006

Re: K060653
Trade/Device Name: ThermaClear
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 24, 2006
Received: July 26, 2006

Dear Mr. Scocimara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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Page 2 -- Mr. Peter Scocimara

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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ThermaClear™ Traditional 510K Document

4. Indications for Use Statement

510(k) Number (if known): K060613

Device Name: ThermaClear

Indications for Use: ThermaClear is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

Page 1 of 1

K060613 Page 7
510(k) Number Proprietary and Confidential

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thermāclear™

Heat Enabled Acne Treatment

User's Guide
Model TC100

PLEASE READ ALL INSTRUCTIONS BEFORE USE

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ThermoClear Model TC100 User's Guide
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INTRODUCTION

At Therative we care about you and your skin.

Therative was established in 2004 with the goal of developing innovative methods for treating acne. After extensive research an idea was born to create a thermal heating device to accelerate the healing time of mild to moderate acne. After many designs and thorough safety testing Therative's ThermoClear™ is ready for your use.

Clinically Proven To Clear Pimples in Less Than Half the Time.

No matter how good your skin care regimen may be, embarrassing pimples still break through. ThermoClear's proprietary Thermal Pulse Technology clears pimples fast. In a clinical study, pimples treated with ThermoClear cleared 2 to 4 times faster than pimples not treated with the device.

ThermoClear works best when applied to new pimples. If you feel a sore bump or see a red spot developing into a pimple, treat it immediately with ThermoClear. Our clinical studies indicate that treating pimples when they first begin to appear gives you the best results. Treat new pimples again 1 – 4 hours later and then follow the normal treatment cycle described on page 11 and following.

Put your best face forward—take control of breakouts today!

HOW DOES THERMACLEAR™ WORK?

What Is ThermoClear?

ThermoClear is a safe, easy to use, hand held device specifically targeted for the treatment of individual pimples. An FDA-reviewed clinical trial has proven that ThermoClear reduces the healing time of mild to moderate acne, clearing pimples in less than half the time.

How Does it Work?

We call it HEAT™ — Heat Enabled Acne Treatment. ThermoClear utilizes a controlled thermal pulse to treat each pimple, similar to laser technology used by dermatologists. Simply apply ThermoClear to each pimple as you notice a new pimple forming. ThermoClear's proprietary Thermal Pulse Technology delivers a short heat pulse that effectively and safely penetrates the skin to accelerate healing. You will feel a tingle or "zap" that tells you the device is working.

Clinical trial results have demonstrated that pimples treated with ThermoClear cleared up in less than half the time vs. pimples not treated with the device...in as little as 2-4 days.

You now have an alternative to expensive products and procedures: ThermoClear.

INDICATIONS FOR USE

Who Should Use *ThermaClear*[™]

ThermaClear uses a short pulse of heat for the treatment of pimples in people with mild to moderate inflammatory acne.

- * Mild acne is defined as several inflamed (red) pimples.
- * Moderate acne is many inflamed (red) pimples and pustules (elevation of skin that is filled with pus).

ThermaClear should **NOT** be used by people with severe nodular or severe cystic acne.

- * Severe nodular acne is inflamed (red) pimples and pustules (elevation of skin that is filled with pus) along with deep nodular lesions (a solid mass that can be felt beneath the skin).
- * Severe cystic acne is described as many nodular lesions with scarring.

These types of acne may require other treatments. Please consult your professional health care provider for treatment options.

CONTRAINDICATIONS

Who Should **NOT** Use *ThermaClear*[™]

Do not use on blackheads and whiteheads. ThermaClear has not been tested or proven effective in treating minor blemishes such as blackheads and whiteheads.

Do not use ThermaClear on skin lesions such as moles, warts or ingrown hairs. ThermaClear should never be used on infected skin areas, open sores or wounds as it may delay or harm the healing process.

ThermaClear should not be used if your skin is sensitive to heat, sun or chemicals as the device utilizes a heated pulse to treat pimples. The device may cause skin damage for people with heat sensitive skin.

TIP



If you are uncertain what type of acne or pimple you have, you can visit our website at: www.thermaclear.com to view photos and explanations of the different types of acne.

You can also visit the American Academy of Dermatology website, AcneNet at: www.skincarephysicians.com/acnenet/acne.html

WARNINGS

STOP using the ThermaClear™ acne device if you develop any adverse reaction and contact your medical professional for advice. Failure to contact a medical professional could result in further adverse reactions.

NEVER use ThermaClear when it is wet.

NEVER use the device if the tip is damaged or broken. Do NOT remove protective blue material on the Treatment Tip. Do not use device if this blue material is missing, scratched or damaged as this may result in injury. Do not attempt to repair the tip. Replace with a new tip before resuming use.

NEVER use the device if the case is cracked or broken. Do not attempt to open the device and/or try to repair.

NOT suitable for use in the presence of flammable mixtures.

DO NOT store ThermaClear near a heat source or subject it to high humidity or direct sunlight as these may damage the device.

DO NOT drop or subject ThermaClear to bumps as this may damage the internal components of the device.

DO NOT open ThermaClear other than to replace the

PRECAUTIONS

batteries in the specified compartment. Any other attempt to open the device may result in an electrical shock and will void the product warranty.

DO NOT use rechargeable batteries with ThermaClear™. Only use fresh, high-quality alkaline AA batteries.

DO NOT use ThermaClear if the surface of the Treatment Tip is scratched or damaged. Please order a replacement tip at www.thermaclear.com.

DO NOT use harsh or abrasive chemicals when cleaning the heating surface of ThermaClear as they may damage the device.

DO NOT use ThermaClear if you are taking prescription medication for the treatment of your acne. Please consult your medical professional if you are on prescription medication.

DO NOT use ThermaClear on severe nodular or cystic acne.

DO NOT use ThermaClear on blackheads or whiteheads.

DO NOT pick or squeeze pimples as this may lead to scarring.

PRECAUTIONS

DO NOT use ThermaClear™ around eyes or lips as these areas are very sensitive and the device may be painful.

DO NOT continue to use ThermaClear if you believe your acne is worse than when you started. If you are concerned about any changes to your skin please consult your medical professional.

DO NOT remove the Treatment Tip while the device is turned on. Make sure you turn off the device before removing the tip.

DO NOT insert any objects or body parts into the open tip or battery chamber. Doing so may result in an electrical shock and will void the product warranty.

ALWAYS clean the tip of the ThermaClear device to reduce the spread of germs.

ALWAYS supervise children who are using ThermaClear. A child's skin is often more sensitive than the skin of an adult. The device may be painful for young children.

SIDE EFFECTS

Our clinical trials indicated no major adverse reactions. Side effects that may occur include brief discomfort due to the heated pulse, redness, dryness or peeling of skin. After each treatment, you may see redness where the tip was applied. This is normal and should quickly fade away.

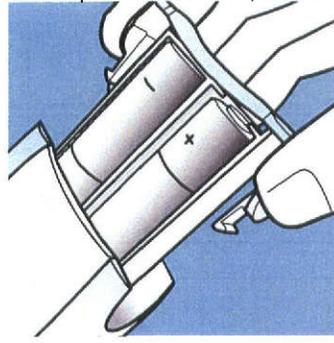
If you notice any additional side effects, we recommend you stop using the device and contact your medical professional for advice.

INSTALLING BATTERIES

The ThermoClear™ TC100 operates on two (2) AA size alkaline batteries. When installing batteries use only fresh, high-quality alkaline batteries and replace both batteries at the same time. Do not use rechargeable batteries or non-alkaline batteries. See Care and Maintenance on page 17 for more information on batteries.

To install batteries:

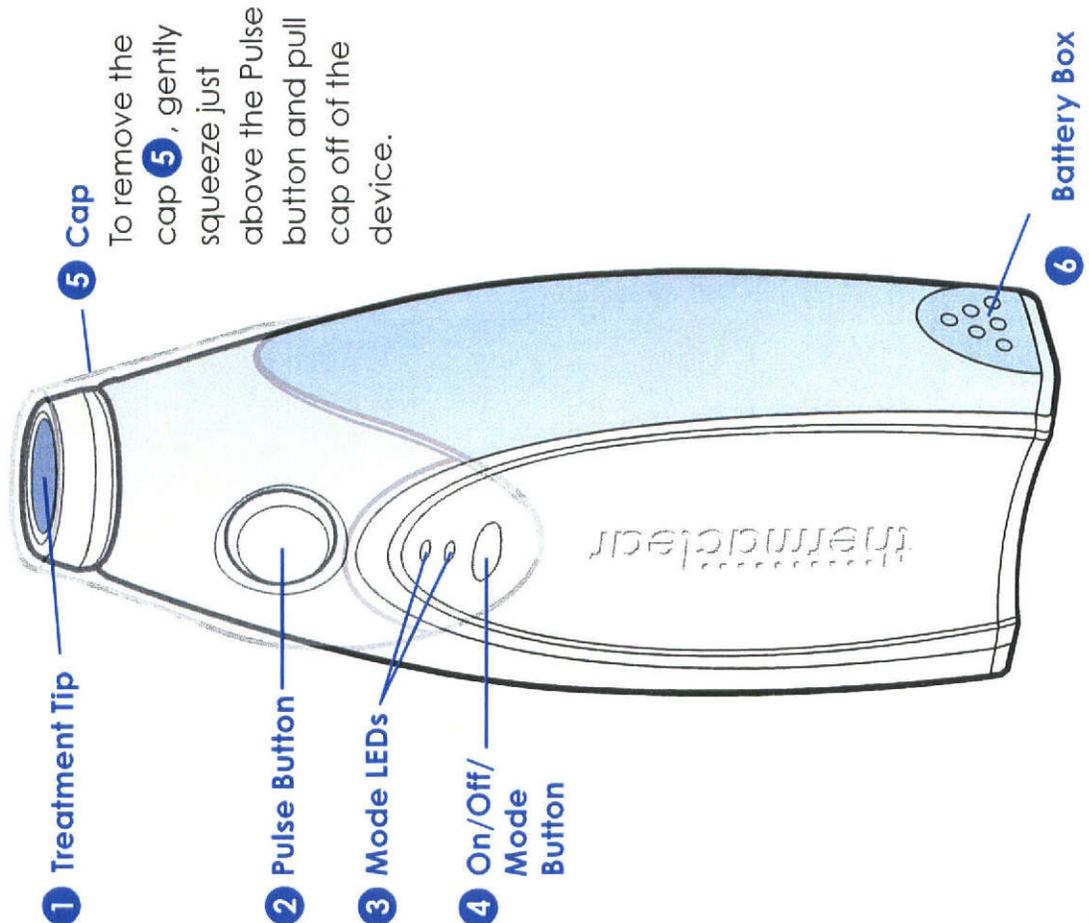
1. Holding the device upside down, remove the battery box **6** by squeezing the side tabs and pulling back.
2. Remove old batteries.
3. Install two (2) new AA alkaline batteries, noting proper polarity (negative and positive) as shown on the battery box.



Re-Insert battery box into ThermoClear.

FIRST STEPS

ThermoClear will not operate if the batteries have been inserted incorrectly. For best results use a cleanser to clean the skin before treatment. Be sure your skin is clean and dry before using ThermoClear. Refer to the Product Diagram on the previous page for help in following these instructions.

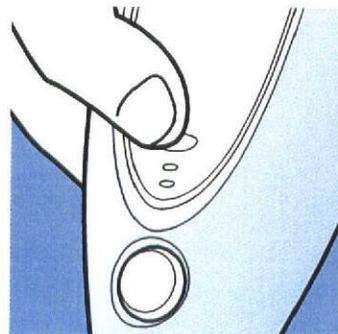
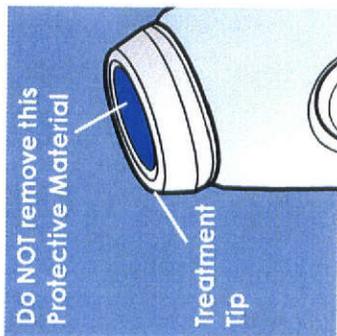


USING THE THERMACLEAR™ TC100

Step 1: Prepare the tip.

Remove clear Cap **5** as described on page 9. Disinfect the Treatment Tip **1** with alcohol.

Warning: Do NOT remove protective blue material on the Treatment Tip. Do not use device if this blue material is missing, scratched or damaged as this may result in injury.



Step 2: Turn on the device.

Turn on the ThermoClear device by pressing and holding the On/Off/Mode button **4** for approximately two (2) seconds. A beep indicates ThermoClear is now on and you can release the button **4**. The device will be charged and ready for use in approximately 10 seconds.

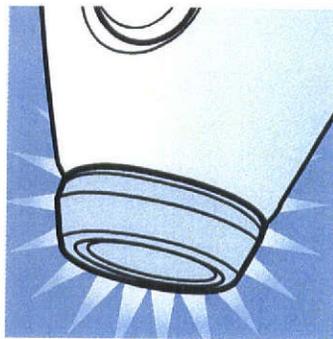
Step 3: Adjust temperature setting.

You may set the device for either LOW or HIGH temperature setting. Pressing the On/Off/Mode button **4** for a fraction of a second toggles between the two settings. One (1) glowing light **3** indicates the temperature is set on LOW; two (2) glowing lights indicates the temperature is set on HIGH.

NOTE: The temperature setting when you turn on the device is the same as the last mode that was used. If the batteries were changed after your last use, the device resets to LOW temperature setting.

TIP: The HIGH temperature mode should be used whenever possible.

Sensitivity to the heat pulse can vary according to the individual and where the Treatment Tip is applied. Certain areas of the face may be more sensitive and it may be necessary to adjust the setting to LOW for those areas. The mode LEDs may flicker slightly when on and charging; this is normal.



Step 4: Ready for use.

Wait for the tip of the device **1** to stop blinking and the sound of a beep, which indicates the device is ready to be used. The device should be charged and ready for use approximately 10 seconds after it is powered on.

USING THE THERMACLEAR™ TC100



Step 5: Apply to pimple.

Using a mirror to guide you, place the Treatment Tip of the ThermoClear™ device on an inflamed pimple and press the Pulse button **2**. You will hear a beep indicating that the heat pulse has been applied. For optimal results, we recommend holding the Treatment Tip against your skin for about two (2) seconds after pressing the Pulse button.

NOTE: When a heat pulse is applied you will feel a mild stinging sensation. In the LOW setting this is a mild sensation. In the HIGH setting and on sensitive areas the sensation may be similar to a pinprick. This stinging sensation is normal and goes away quickly. It also means that the ThermoClear device is working, sending heat to attack the source of your pimple. After the heat pulse is delivered, the Treatment Tip will blink again.

Step 6: Remove from pimple.

Remove ThermoClear from the pimple. You may notice some skin redness where the tip was applied. This is normal and should fade away quickly.

Step 7: Repeat on other pimples.

If you would like to treat another pimple, repeat Step 4 through Step 6. It will take about 8 seconds for the device to recharge before your next application. The device is ready when the tip stops blinking.

Step 8: Turn off and store device.

When you have finished all treatments press the On/Off/Mode button **4** for approximately two (2) seconds until you hear a beep and the mode LEDs **3** turn off. If necessary, disinfect the tip and place the protective cap **5** on ThermoClear™ and store the device.

ThermoClear works best at the first sign of a pimple. As soon as you notice a pimple, cleanse the pimple, and treat with ThermoClear. Try to cleanse and treat each new pimple again within 1 – 4 hours.

You may treat a pimple 1 – 3 times in a 24-hour period. Do not treat the same pimple more than once in a one (1) hour period. Do not exceed three (3) treatments per pimple in a 24-hour period. Excessive treatments may delay healing or burn your skin.

HELPFUL ADVICE

- * It is helpful to use a mirror when using ThermoClear™ to insure proper placement of the tip on each pimple.
- * Place ThermoClear gently on each pimple. It is not necessary to use excessive pressure when making contact.
- * Facial hair may interfere with contact and limit the effectiveness of ThermoClear.
- * If you are fair skinned you may experience more redness around the treatment areas. This should not be excessive and is no cause for alarm. If you experience a serious adverse reaction while using ThermoClear, stop using the device and consult a medical professional.

TROUBLESHOOTING

My ThermoClear™ will not power on when I press the power button. Make sure that you press the On/Off/Mode button for at least two (2) seconds. If the mode LEDs do not light when you press the On/Off/Mode button then you may need new batteries or the batteries have not been installed properly. Refer to page 10, *Installing Batteries*.

The Tip LEDs do NOT STOP blinking. Press the On/Off/Mode button and the Pulse button to make sure the buttons are not stuck. If this does not solve the problem then you most likely need to replace the batteries.

After treating a pimple my ThermoClear will not emit another heat pulse. You must allow the device time to recharge between each treated pimple. The recharge time is about 8 seconds. When the tip LEDs stop blinking and stay on continuously, the ThermoClear device is charged and ready to treat another pimple.

My ThermoClear is taking more than 10 seconds to recharge between treatments. You may need new batteries. Refer to page 10, *Installing Batteries*.

CARE AND MAINTENANCE

Cleaning.

During normal use the ThermoClear™ Treatment Tip should be disinfected before treatment using a clean damp cloth and alcohol. If necessary the protective cap and plastic case of ThermoClear can also be cleaned using a cloth and soapy water. The cloth should only be moist and NOT dripping wet to reduce any risk of water entering the device.

Avoid using abrasive cleansers that could scratch and damage the surface of ThermoClear.

The typical procedure to clean the tip is to disinfect with 70% isopropyl alcohol.

Do NOT immerse ThermoClear in any liquid.

Battery Information.

During normal use ThermoClear only requires changing batteries as necessary. When changing batteries, utilize high-quality alkaline batteries. DO NOT use rechargeable batteries.

ThermoClear will emit a warning notice (three short "beeps" before indicating it is charged) to notify you that your batteries are running low. When you hear this warning, you

will only have a few charges left; turn off the device and replace the old AA batteries with a fresh set of high-quality alkaline batteries.

When your batteries are no longer usable, the device will emit four long beeps, then power will shut off. You will need to insert fresh high-quality alkaline AA batteries before you will be able to use the device.

We recommend removing the batteries if the device is not likely to be used for 3 months or if the device will be shipped via mail.

To properly dispose of used batteries, please refer to your local codes.

Storage.

Always store the ThermoClear™ device in a dry place at temperatures between 40 and 100 degrees (F). Keep ThermoClear away from heat, humidity, or harmful chemicals.

Avoid direct exposure to sunlight to protect the plastic components.

CARE AND MAINTENANCE

TECHNICAL SPECIFICATIONS

Replacement Tips.

We recommend replacing the Treatment Tip at least once a year. You should replace the Treatment Tip immediately if it is scratched or damaged. A replacement Treatment Tip can be purchased at www.thermaclear.com.

Removing the Treatment Tip other than to replace it is not advised. Directions for replacing the Treatment Tip are provided when you receive a new tip.

When disposing of the device tip, disinfect with 70% isopropyl alcohol.

Do not drop or subject the ThermoClear™ to strong shocks.

Device Disposal.

When disposing of the device, remove the batteries, disinfect the device by wiping it with 70% isopropyl alcohol, and dispose of it according to your local codes for electronic devices.

Technical Description.

- **Power rating:** Internally powered by (2) AA alkaline batteries
- **Size:** 4.9 x 2.1 x 1.1 inches
- **Weight:** 4.3 oz (with batteries)
- **Treatment temperature modes:** Low and High
- **Rapid charge time:** 5 seconds, typical in high mode
- **Auto Shut Off**
- **Battery life:** approx. 200 pulses depending on usage
- **Safety:** complies with UL60601-1 and EN60601-1
- **Type BF:** applied part
- **Mode of operation:** continuous
- **Environment:**
 - **Operating:** 10C to 40C (50F to 104F), 0-90% RH
 - **Storage:** -20C to 50C (-4F to 122F), 0-90% RH
- **Protection against ingress of water:** ordinary protection

GUIDANCE AND MANUFACTURER'S DECLARATION

SYMBOLS GLOSSARY

Table 201: For Therative ThermoClear™ TC100
**Guidance and manufacturer's declaration –
 electromagnetic emissions**

The ThermoClear TC100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model TC100 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The ThermoClear TC100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model TC100 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable (Battery Powered)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable (Battery Powered)	



Internally powered Type BF applied part



Warning



Meets TUV Test requirements for safety

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216-1

LIMITED 90-DAY WARRANTY

The ThermoClear™ TC100 is warranted to be free from defects in materials and workmanship for a period of 90 days from date of original purchase under normal use. This warranty extends only to the original retail purchaser and only when purchased from an authorized retailer.

If the product should become defective during the warranty period, please contact Therative, Inc., Customer Service at 800.604.6403 for repair or replacement. Therative reserves the right to replace a defective product with the most comparable product currently available.

This warranty does not cover products damaged by the following:

- * **Accident, misuse, abuse or alteration**
- * **Servicing by unauthorized persons**
- * **Use with unauthorized accessories**
- * **Any other condition beyond our control**

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Therative, Inc.

6248 Preston Avenue

Livermore, CA 94551

Phone: 925.371.3900

Fax: 925.371.3903

Customer Service: 800.604.6403

www.thermaclear.com

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The name ThermaClear and HEAT are trademarks of
Therative, Inc. Patents pending

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ThermaClear Device

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ThermaClear in the News

Read what the press has to say about ThermoClear.

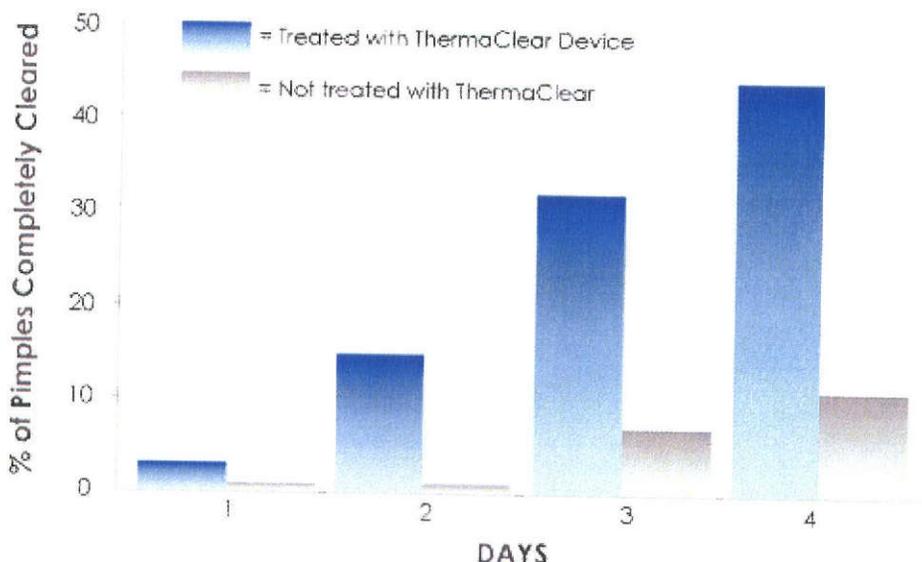
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ThermaClear Clinical Study Results

In an FDA-reviewed clinical study, pimples treated with ThermoClear™ cleared 2 – 4 times faster than untreated pimples - without any harmful side effects.

Study Results

The following chart shows the results from the FDA-reviewed study. In that study, two independent dermatologists evaluated all inflamed acne lesions, both treated and untreated, and scored them based on severity over 5 days in order to assess how well ThermoClear resolved (cleared) pimples. Pimples treated with ThermoClear (shown in blue) cleared up to 4 times faster than pimples not treated with ThermoClear (shown in gray). Put another way, pimples treated with ThermoClear resolved in less than half the time of pimples not treated with ThermoClear.



Safety Results

A total of 46 patients completed at least 4 days of treatment or more. No adverse events occurred during the five-day trial, and no adverse events were uncovered in the follow-up interviews. There were no device complications reported during the study.

In addition, 20 patients participated in an extended at-home trial of on-going use. This at-home use ran from 14 to 28 days, depending on participant. No harmful side effects were reported. In addition, trials conducted involving anti-acne topical treatments indicated using the device with benzoyl peroxide (the most common over-the-counter anti-acne medicine) showed no adverse effects or reactions. No post-study complications or adverse events have been reported.

Study Methodology

In order to test the effectiveness of this product and verify its safety for use by consumers, the makers of ThermoClear performed a clinical study of the device on 46 adults and adolescents. The study took place under the guidance of a board-certified dermatologist at the Berman Skin Institute in Palo Alto, California.

The participants in the study represented a balance of gender (60% female, 40% male)

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Records processed under FOIA Request # 2013-5590; Released by CDRH on 8/6/2015

and a distribution of age and ethnicity (see table below for details). For each participant, acne lesions on one side of their face were treated with the ThermaClear device while pimples on the other side were left untreated as "controls" (comparison). Each participant was treated once daily with the ThermaClear device over the course of five days. All participants' faces were cleansed daily, after which we performed the following:

1. For treated lesions, we applied the ThermaClear acne treatment device and treated the area with a single thermal pulse once daily.
2. Untreated lesions were simply left alone.

Patient Demographics

Attribute	Mean ± SD or N (%)
Age (years)	25.3 ± 7.6
Gender	
Male	20 (40%)
Female	28 (60%)
Ethnicity	
White	26 (54%)
African American	5 (10%)
Hispanic or Latino	7 (15%)
Asian	10 (21%)
Lesions treated	278
Lesions Not Treated	152

The lesions selected for testing and monitoring represented a broad range of stages of acne development (i.e., range of severity, stage of development, etc.). Each lesion was rated and "scored" in terms of severity of development at the outset of the clinical study and throughout the study. To ensure objective and clear ratings, two independent, blinded dermatologists analyzed photographs of a total of 430 lesions (278 treated and 152 NOT treated). These observers graded the lesions and determined a score for each lesion for each day of the 5-day trial. The scores for treated and untreated lesions were then tabulated and compared on a patient by patient basis to remove any sample bias.

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The name ThermaClear is a trademark of Therative, Inc. Patents pending.

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ThermaClear for Acne

The FDA has approved *ThermaClear* (Therative), a battery-powered, handheld device, to treat individual acne lesions with heat. *ThermaClear* is indicated only for use on mild to moderate inflammatory acne, not severe nodular or severe cystic acne, and it is not meant to be used on blackheads and whiteheads. Two similar devices are already on the market: *Zeno*, another handheld device that delivers heat to acne lesions, and the *Radiancy Clear Touch Lite Acne Clearance System*, a larger heat-delivery device.

TREATMENT OF ACNE — Depending on the severity and type of acne, standard treatment options range from topical drugs to systemic therapy with antibiotics or retinoids. Topical salicylic acid and benzoyl peroxide, which are both available over the counter (OTC), are often tried first. The other topical drugs, sometimes used in combination, include azelaic acid (*Azelex*), erythromycin (*Eryderm*, and others), clindamycin (*Cleocin*, and others) and other antimicrobials that decrease colonization with *Propionibacterium acnes*, and retinoids such as tretinoin (*Retin-A*, and others), adapalene (*Differin*) and tazarotene (*Tazorac*).

The retinoids have anti-inflammatory and comedolytic properties, and prevent formation of new comedones. The systemic antibiotics most commonly prescribed to treat acne are the tetracyclines, including doxycycline (*Monodox*, and others) and minocycline (*Minocin*, and others). The oral retinoid isotretinoin (*Accutane*, and others) is used to treat severe recalcitrant nodular acne. Oral contraceptives are commonly used to treat acne in women.¹

MECHANISM OF ACTION — The mechanism of action of the new device is unclear. According to the manufacturer, a burst of heat from the device delivered as a short thermal pulse directly to an inflammatory acne lesion accelerates the resolution of the lesion without burning the skin.

USING THE DEVICE — *ThermaClear* has low and high heat settings. It usually takes about 10 seconds to power up after being turned on and about 8 seconds to recharge between each pulse. After pressing the pulse button, the device will beep to indicate that the heat pulse has been applied to the targeted area. According to the manufacturer, *ThermaClear* works best when applied directly to new acne lesions, even as they develop, with a second application 1-4 hours later; lesions can be treated up to a maximum of 3 times a day. The device's tip should be disinfected with 70% isopropyl alcohol before each use and placed flush with the lesion when the heat pulse is applied.

CLINICAL STUDIES — Approval of *ThermaClear* was based on one 5-day clinical study in 46 patients (adults and adolescents). Acne lesions on one side of the face were treated once daily with the device, while the other side of the face was not treated (no sham treatment); two independent dermatologists unaware of which side was treated evaluated and scored the 430 treated and untreated acne lesions in photographs at baseline and throughout the study. By day 4, 44% of treated lesions had resolved compared to 11% of untreated lesions.²

ADVERSE EFFECTS — No adverse effects or severe reactions have been reported with the device. The heat pulse can cause brief discomfort—a temporary stinging sensation on the low setting and a pinprick on the high setting. Slight redness, especially in fair skinned patients, may occur after treatment, but dissipates quickly. The device should not be used on skin that is sensitive to heat, sun or chemicals, or around the eyes or lips.

COST — The *ThermaClear* device costs \$149.95.³ It can be purchased alone or in combination with topical skin care and acne treatment products offered by the same manufacturer. The tip of the device should be replaced at least once a year, according to the manufacturer, at a cost of about \$20.

CONCLUSION — *ThermaClear*, a handheld device that delivers a heat pulse, might be helpful for treatment of

individual lesions of mild to moderate inflammatory acne, but no adequate studies have been done, no published data are available, and its long-term effects, such as possible scarring, are unknown. □

1. Drugs for acne, rosacea and psoriasis. Treat Guidel Med Lett 2005; 3:49.
2. ThermaClear clinical study results. Available at www.thermaclear.com. Accessed June 11, 2007.
3. Price according to the manufacturer.

Coming Soon in *The Medical Letter*:

Lisdexamfetamine dimesylate (*Vyvanse*) for ADHD
Arformoterol (*Brovana*) for COPD
Lybrel – A New Contraceptive Pill

Coming Soon in *Treatment Guidelines*:

Drugs for Non-HIV Viral Infections — July 2007
Drugs for Allergic Disorders — August 2007
Drugs for Sexually Transmitted Infections —
September 2007

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27 March 2007

Therative/ThermaClear Overview

Company Overview

- Therative based in Livermore CA, USA with offices in San Francisco.
- The founder of the company is Peter "Scotch" Scocimara.
- The company currently produce one product "ThermaClear"
- This product is based on a Patent application 20060142750 from 29/06/2006.
- The total capital raised by the company is \$5M.
- Primary investors are Foundation Capital, RWI Ventures and Band of Angels
- "ThermaClear" received FDA clearance to market on 24/10/2006
- In Febuary 2007 CDS Inc. was appointed to provide direct-to-customer sales, fulfillment, distribution and customer care for all of the USA.
- In February 2007 the company appointed a PR agency and a Marketing agency

Products Overview



ThermaClear \$149.95



ThermaClear Essentials Sets \$54.95

Patent Overview

1. Patent Application - 20060142750

- **Title**
Device and method for treatment of skin conditions.

- **Abstract**
The device and method are based on the delivery of controlled pulses of thermal energy causing a biological response that accelerates healing.

- **Main Claims**
 - a) A heating element adapted and configured to contact a skin surface.
 - b) Two main modes:
 - ⇒ A pulse of heat at of 70 °C for less than 1 sec.
 - ⇒ A pulsed of heat with peak temperature of 250 °C within 1 msec, that decays to 100 °C in less than 0.5 sec.
 - c) Automatic re-heating of the element after the delivery of the pulse.
 - d) Hand held device.
 - e) Total Energy transferred to the skin, < 5 J/cm² or < 50 J/cm².

2. ThermaClear Whitepaper

- 46 Patients enrolled in the trail.
- Daily treatment
- Lesions Resolved:

✓ After #1 treatment:	<u>ThermaClear 3%</u>	<u>Placebo 1%</u>
✓ After #2 treatment:	<u>ThermaClear 15%</u>	<u>Placebo 1%</u>
✓ After #3 treatment:	<u>ThermaClear 32%</u>	<u>Placebo 7%</u>
✓ After #4 treatment:	<u>ThermaClear 44%</u>	<u>Placebo 11%</u>
✓		

3. ThermaClear510K approval # K0460653 approval date 24 October 2006

- Substantially equivalent predicate devices:
 - ✓ Tyrell Inc. – Zeno K043377
 - ✓ Radiancy – ClearTouch Light K032205
- Description of the device:
 - ✓ A portable hand-held device that uses a short thermal pulse to treat mild to moderate inflammatory acne.
 - ✓ The treatment tip is comprised of biocompatible material.
 - ✓ The device is powered by two AA alkaline batteries (not rechargeable)
- Indications for use:
 - ✓ For the treatment of individual acne pimples.
 - ✓ Over-The-Counter Use (OTC)

4. ThermaClear Distribution

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Currently only in company's website <http://www.thermaclear.com>

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THE HEAT IS ON – Published in USA today 12/02/2007

There are a hundred ways to fight acne, including lasers, creams, cleansers, pads and masks.

Get ready to add another to the list: heat.

Two devices are on the market in the USA that try to discourage pimples by zapping them with heat: Zeno, a device from Houston-based Tyrell Inc., and ThermaClear by Therative, based in Livermore, Calif.

But do they work?

"There's not a lot of studies out there," says Darrell Rigel, dermatologist and professor at New York University. "But it may be something to try"



Zeno



ThermaClear

Zeno heats to a temperature of 118.5 degrees, which is warm to the skin but "well below the threshold that causes burning," says Robert Conrad, Tyrell's founder and chief operating officer.

Conrad says that level of heat doesn't burn *P. acnes* bacteria, which cause 90% of acne, but causes a "heat shock response" in which the bacteria retreat to a smaller colony when confronted by a threatening environment.

ThermaClear heats up to 212 degrees Fahrenheit. But it's applied for just 21/2 seconds vs. 21/2 minutes for Zeno, says Peter Scocimara, CEO of Therative. Jeanine Downie, a New Jersey-based dermatologist and consultant to ThermaClear, says the device activates heat-stabilized proteins and reduces inflammation.

The idea behind both devices is that a pimple will shrink more quickly and have less chance of developing into a dreaded whitehead

But if you do develop a whitehead, there may not be much either device can do. At that point the body has begun to fight the infection itself, so heat would do nothing to speed the process along, says Allison Allison, spokeswoman for Tyrell

The price tag may keep some consumers away: \$149 for Zeno, which works for 60 treatments, and \$25 for replacement tips

ThermaClear retails for \$149.95 and needs replacement tips twice a year or sooner if scratched or damaged, for \$20 apiece.



COVER SHEET MEMORANDUM

From: Reviewer Name Kareem S. Burney
 Subject: 510(k) Number 108203/57
 To: The Record

Please list CTS decision code NSE
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist <http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ScreeningChecklist>)
 Hold (Additional Information or Telephone Hold).
 Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III? If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATEDSTANDARDSDATAFORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		

Regulation Number 878.4810 Class* II Product Code GEX
 (*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Kareem S. Burney 65DB 11/21/08
 (Branch Chief) (Branch Code) (Date)
 Final Review: [Signature] [Signature] 11/24/08
 (Division Director) (Date)

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):	YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)		
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?		
3. Does this device type require a PMA by regulation? (Please see management.)		
Questions 4-8 are intended to help you start your review:	YES	NO
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)		
5. a. Did the firm request expedited review? (See management,)		
b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html)		
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:	
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:	
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html)		



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K082423

Date: November 21, 2008
To: The Record
From: Kareem S. Burney, M.S.

Office: ODE
Division: DGRND

510(k) Holder: Radiancy LTD
Device Name: No! No! Skin
Contact: Zvi Ladin
Phone: (781) 407-0900
Fax: (781) 407-0901
Email:

I. Purpose and Submission Summary

The 510(k) holder would like to introduce No! No! Skin into interstate commerce.

III. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include: Indications for Use page (Indicate if: Prescription or OTC), Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, Standards Form.

III. Device Description

Table with 4 columns: Question, Yes, No, N/A. Rows include: Is the device life-supporting or life sustaining?, Is the device an implant (implanted longer than 30 days)?, Does the device design use software?, Is the device sterile?, Is the device reusable (not reprocessed single use)?, Are "cleaning" instructions included for the end user?

- This device is a portable 6 VDC battery-powered, hand-held device.
The treatment cycle delivers a series of broad spectrum light pulses to a single acne lesion.
The energy delivered to the lesion is a combination of focused light emitted from the halogen

lamp together with heat accumulated in the chamber placed over the acne lesion.

II. Indications for Use

No! No! Skin is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Sponsor should indicate that this device is for OTC use.

III. Predicate Device Comparison

ClearTouch Light Unit Assembly by Radiancy Ltd (K032205)
Zeno Acne Treatment System by Tyrell, Inc (K043377)
ThermaClear Acne Treatment Device by DermaCare (K060653)

There are some differences between this device and the predicate device K043377 and K060653 use only heat to treat acne while K060411 uses both heat and light but is a prescription device. Between the comparison between this device and K060411, the wavelengths are different: This device has a wavelength range of 450 – 2000 nm and K060411 has a wavelength range of 430 – 1100 nm. The energy delivery duration is different between the two devices the current device has a duration of 10 sec and K060411 has a duration of 6 sec. The spot size is different but the max fluence is the same.

IV. Labeling

Device diagrams, box labels, instructions for use has been included in the submission.

The recommended treatment schedule is two sessions a day, 6-12 hours apart until the pimple heals. Threat only one pimple a time and treat each pimple twice per session. One treatment last 10 seconds and wait 5 seconds before treating the pimple a second time. (So each pimple will be treated for a total of 20 seconds).

V. Sterilization/Shelf Life/Reuse

This device is provided non sterile. Cleaning instructions has been included in the instruction for use.

VI. Biocompatibility



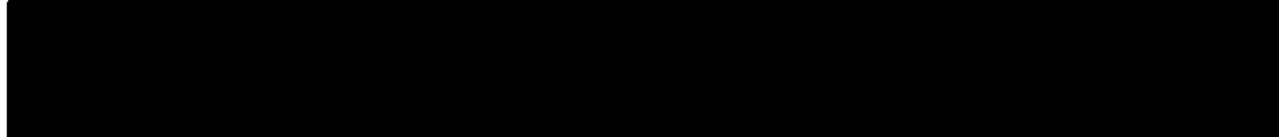
VII. Software

Software is included in this device.

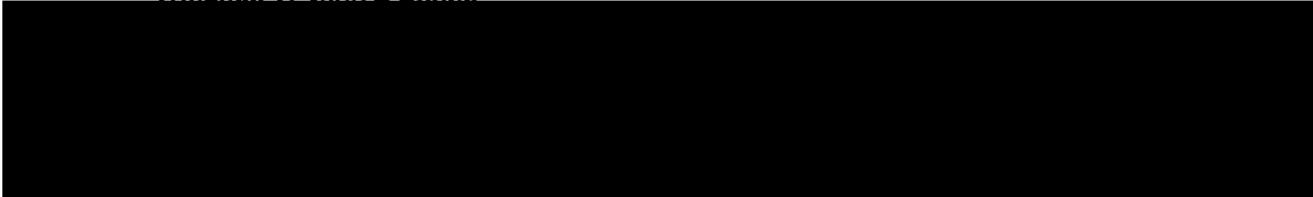
The sponsor needs to determine the level of concern and the documentation for that level of concern. That information can be found here: <http://www.fda.gov/cdrh/ode/guidance/337.html>.

Version:	
Level of Concern: Minor	
Software description:	
Device Hazard Analysis:	
Software Requirements Specifications:	
	Yes No

Architecture Design Chart:	
Design Specifications:	
Traceability Analysis/Matrix:	
Development:	
Verification & Validation Testing:	
Revision level history:	
Unresolved anomalies:	

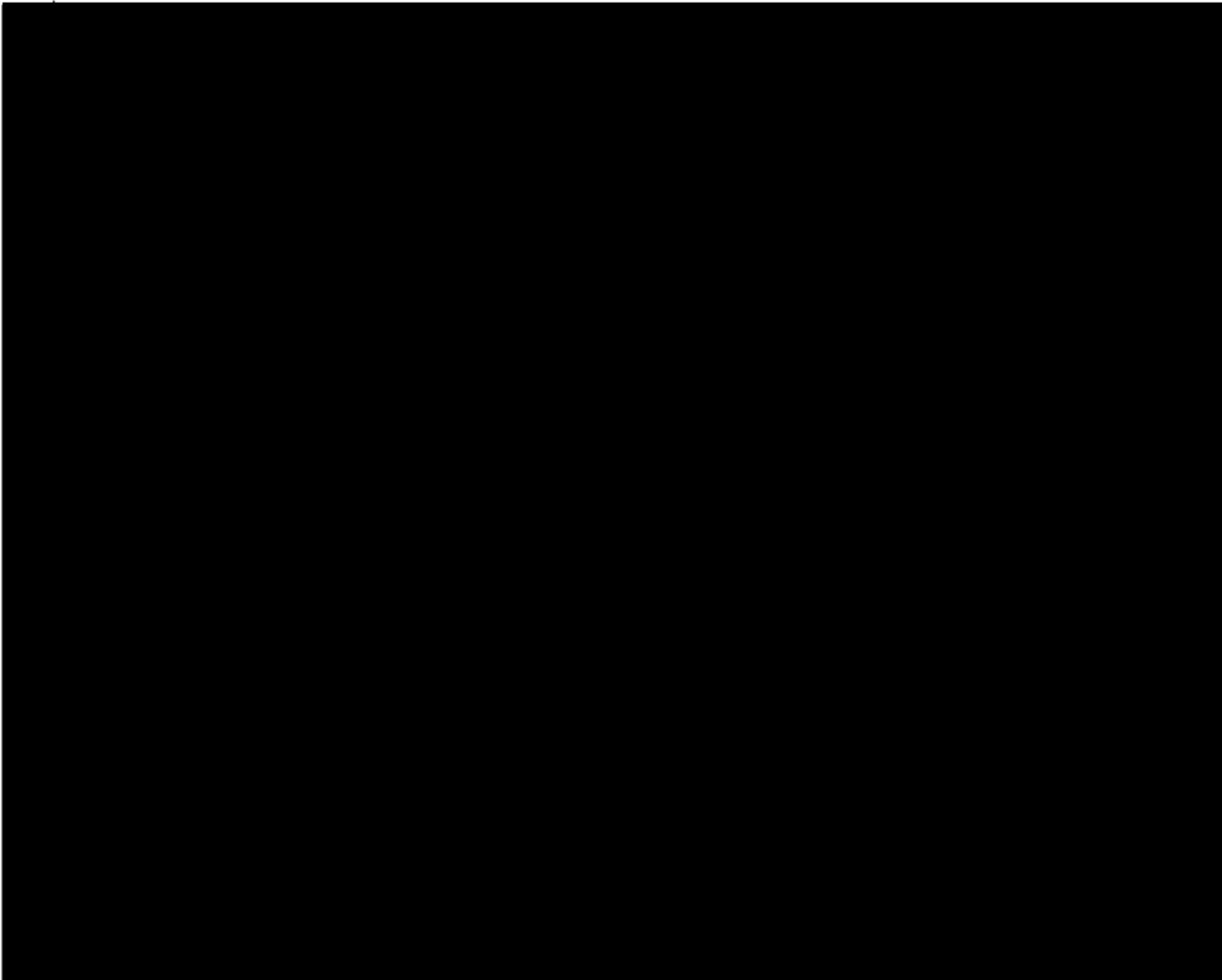


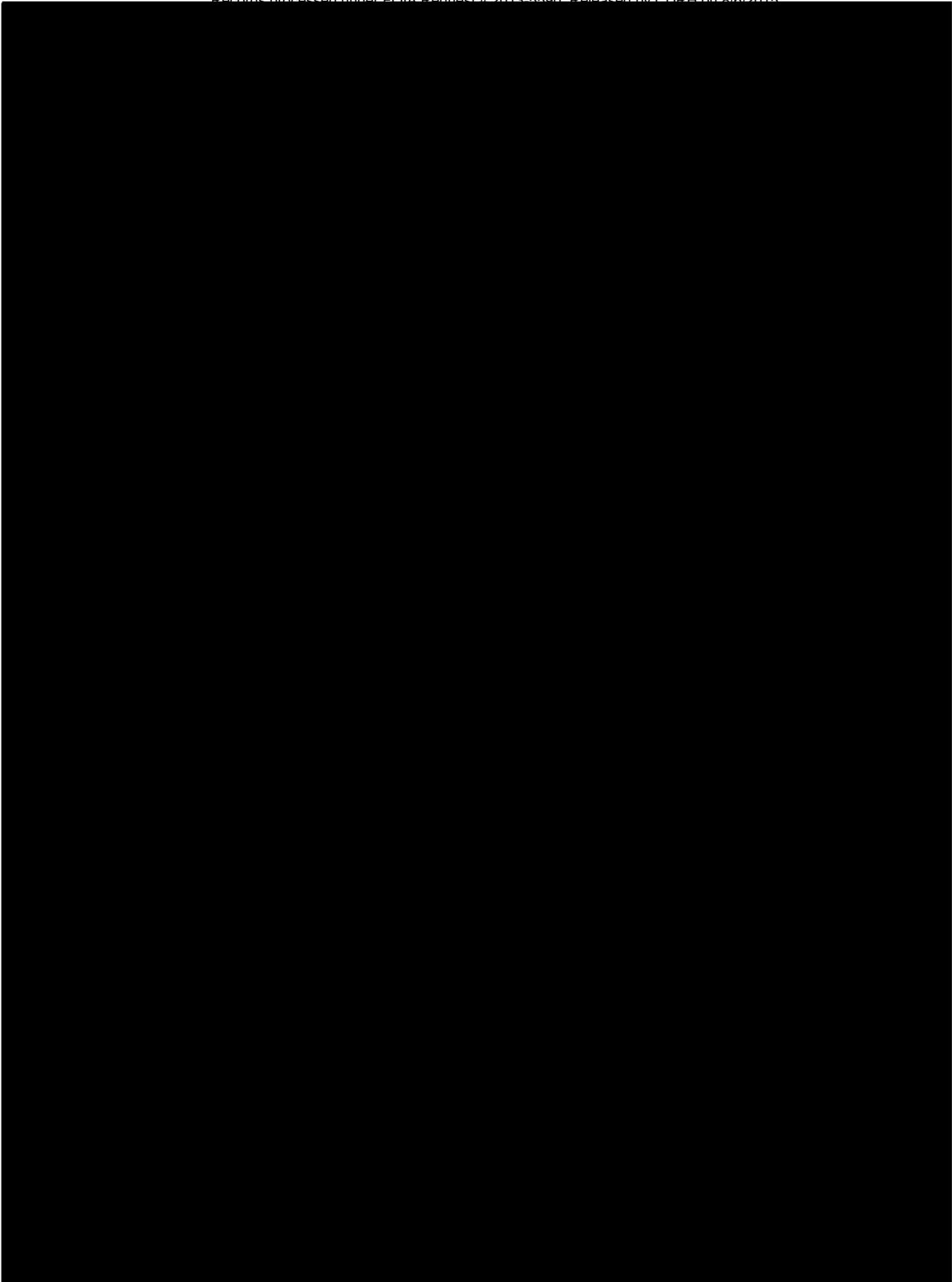
IX. Performance Testing – Bench



X. Performance Testing – Animal

XI. Performance Testing – Clinical





XII. Substantial Equivalence Discussion

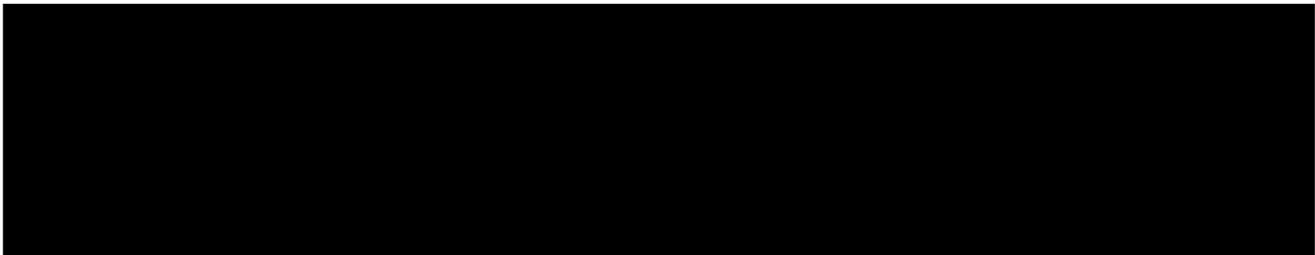
	Yes	No
1. Same Indication Statement?		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision:

Note: See

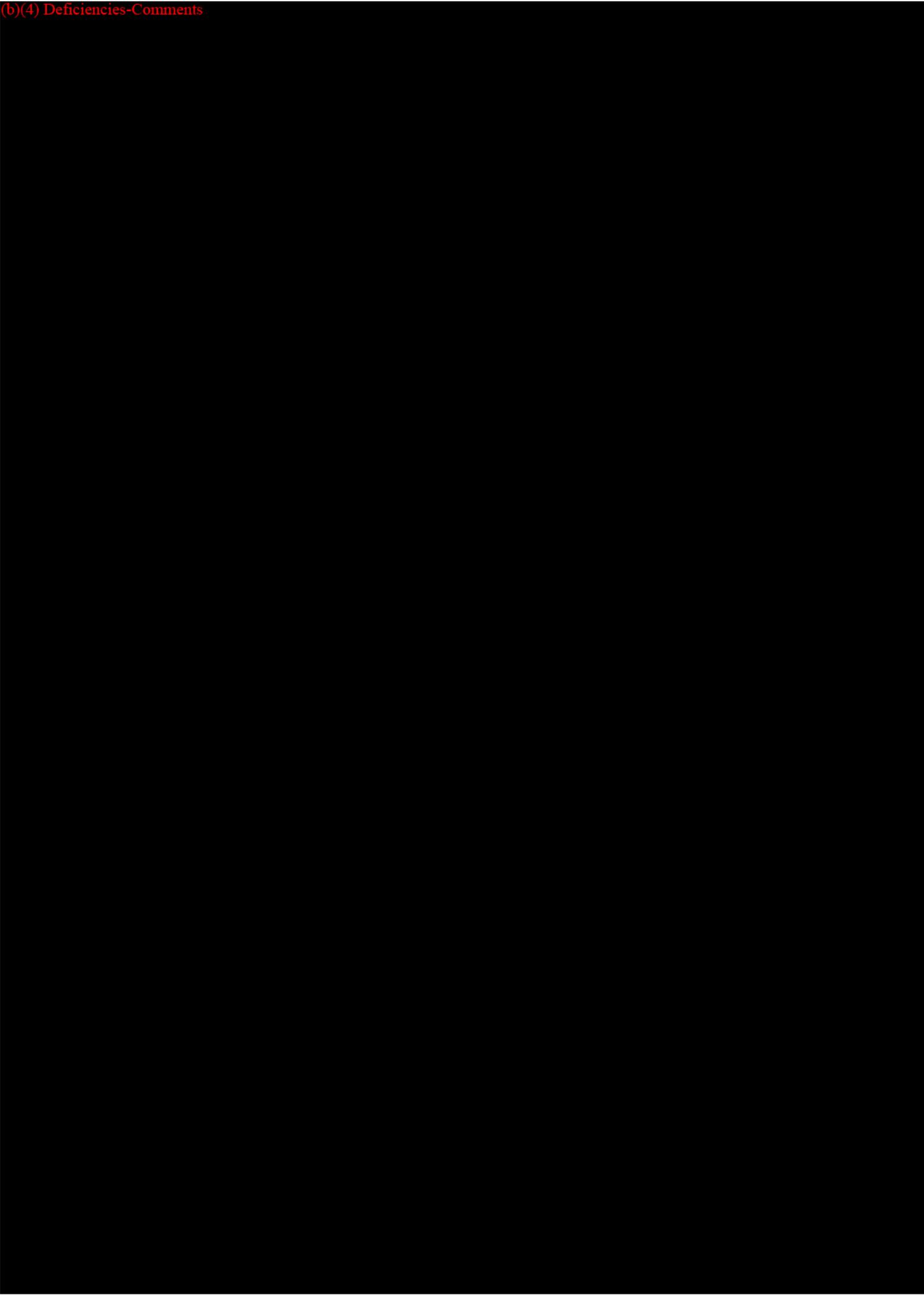
http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies



(b)(4) Deficiencies-Comments



XV. Recommendation

This file is found not substantially equivalent to the predicate device.

Regulation Number:
Regulation Name:
Regulatory Class:
Product Code:

Karen S. King
Reviewer

11/24/08
Date

Branch Chief

Date

Burney, Kareem

From: Rosecrans, Heather S.
Sent: Tuesday, November 18, 2008 6:36 PM
To: Burney, Kareem; Melkerson, Mark N.; Ogden, Neil
c: Shulman, Marjorie G.; Stuart, Julie (Brandi)
Subject: NSE Letter K082423.doc

Attachments: NSE Letter K082423.doc

Hi Kareem,
I made a few suggested edits. Are we near the 90 days for this 510k? Thanks.
Heather



NSE Letter
K082423.doc (49 KB)

Burney, Kareem

From: Stuart, Julie (Brandi)
Sent: Tuesday, November 18, 2008 9:57 AM
To: Burney, Kareem
Cc: Ogden, Neil; Rosecrans, Heather S.
Subject: RE: NSE Letter for K082423

Hi Kareem

Heather will be in later this morning, but just at a glance it looks good to me.

Since it is NSE for lack of data you can use the existing appropriate product code.

Please let me know if you have any questions.

Thanks
Brandi

Julie "Brandi" Stuart

Consumer Safety Officer

Office of Device Evaluation/510(k) Staff

240-276-4020

Snowflakes are fragile things

But look at what they can do when they stick together

From: Burney, Kareem
Sent: Tuesday, November 18, 2008 7:43 AM
To: Stuart, Julie (Brandi)
Cc: Ogden, Neil
Subject: NSE Letter for K082423

Brandi,
Heather and Marjorie arent in. Is this NSE Letter ok? Please let me know if it is acceptable.

Kareem

From: Burney, Kareem
Sent: Monday, November 17, 2008 10:25 AM
To: Rosecrans, Heather S.; Shulman, Marjorie G.
Cc: Ogden, Neil; Melkerson, Mark N.
Subject: NSE Letter for K082423

Heather,
I want to recommend NSE for this file. The letter attached to this e-mail. Please let me know if it is acceptable.

<< File: NSE Letter K082423.doc >>

Kareem S. Burney, M.S.

*Acting Branch Chief
General Surgery Devices Branch
Division of General, Restorative and Neurological Devices
Food and Drug Administration
9200 Corporate Blvd
Rockville, MD 20850
Phone# (240) 276-3609
E-mail:kareem.burney@fda.hhs.gov*



COVER SHEET MEMORANDUM

From: Reviewer Name Kareem S. Burney
Subject: 510(k) Number K082423 / SI
To: The Record

- Please list CTS decision code AI
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ?			
(If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K082423

Date: October 20, 2008
To: The Record
From: Kareem S. Burney, M.S.

Office: ODE
Division: DGRND

510(k) Holder: Radiancy LTD
Device Name: No! No! Skin
Contact: Zvi Ladin
Phone: (781) 407-0900
Fax: (781) 407-0901
Email:

I. Purpose and Submission Summary

The 510(k) holder would like to introduce No! No! Skin into interstate commerce.

III. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, and Standards Form.

III. Device Description

Table with 4 columns: Question, Yes, No, N/A. Rows include questions about life-supporting, implant, software, sterile, reusable, and cleaning instructions.

- This device is a portable 6 VDC battery-powered, hand-held device.
The treatment cycle delivers a series of broad spectrum light pulses to a single acne lesion.
The energy delivered to the lesion is a combination of focused light emitted from the halogen

lamp together with heat accumulated in the chamber placed over the acne lesion.

II. Indications for Use

No! No! Skin is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Sponsor should indicate that this device is for OTC use.

III. Predicate Device Comparison

ClearTouch Light Unit Assembly by Radiancy Ltd (K032205)

Zeno Acne Treatment System by Tyrell, Inc (K043377)

ThermaClear Acne Treatment Device by DermaCare (K060653)

There are some differences between this device and the predicate device K043377 and K060653 use only heat to treat acne while K060411 uses both heat and light but is a prescription device. Between the comparison between this device and K060411, the wavelengths are different: This device has a wavelength range of 450 – 2000 nm and K060411 has a wavelength range of 430 – 1100 nm. The energy delivery duration is different between the two devices the current device has a duration of 10 sec and K060411 has a duration of 6 sec. The spot size is different but the max fluence is the same.

IV. Labeling

Device diagrams, box labels, instructions for use has been included in the submission.

The recommended treatment schedule is two sessions a day, 6-12 hours apart until the pimple heals. Threat only one pimple a time and treat each pimple twice per session. One treatment last 10 seconds and wait 5 seconds before treating the pimple a second time. (So each pimple will be treated for a total of 20 seconds).

V. Sterilization/Shelf Life/Reuse

This device is provided non sterile. Cleaning instructions has been included in the instruction for use.

VI. Biocompatibility

(b)(4) CCI

VII. Software

Software is included in this device.

The sponsor needs to determine the level of concern and the documentation for that level of concern. That information can be found here: <http://www.fda.gov/cdrh/ode/guidance/337.html>.

Version:		
Level of Concern: Minor		
Software description:		Yes No
Device Hazard Analysis:		
Software Requirements Specifications:		

Architecture Design Chart:	
Design Specifications:	
Traceability Analysis/Matrix:	
Development:	
Verification & Validation Testing:	
Revision level history:	
Unresolved anomalies:	

(b)(4) CCI



IX. Performance Testing – Dental

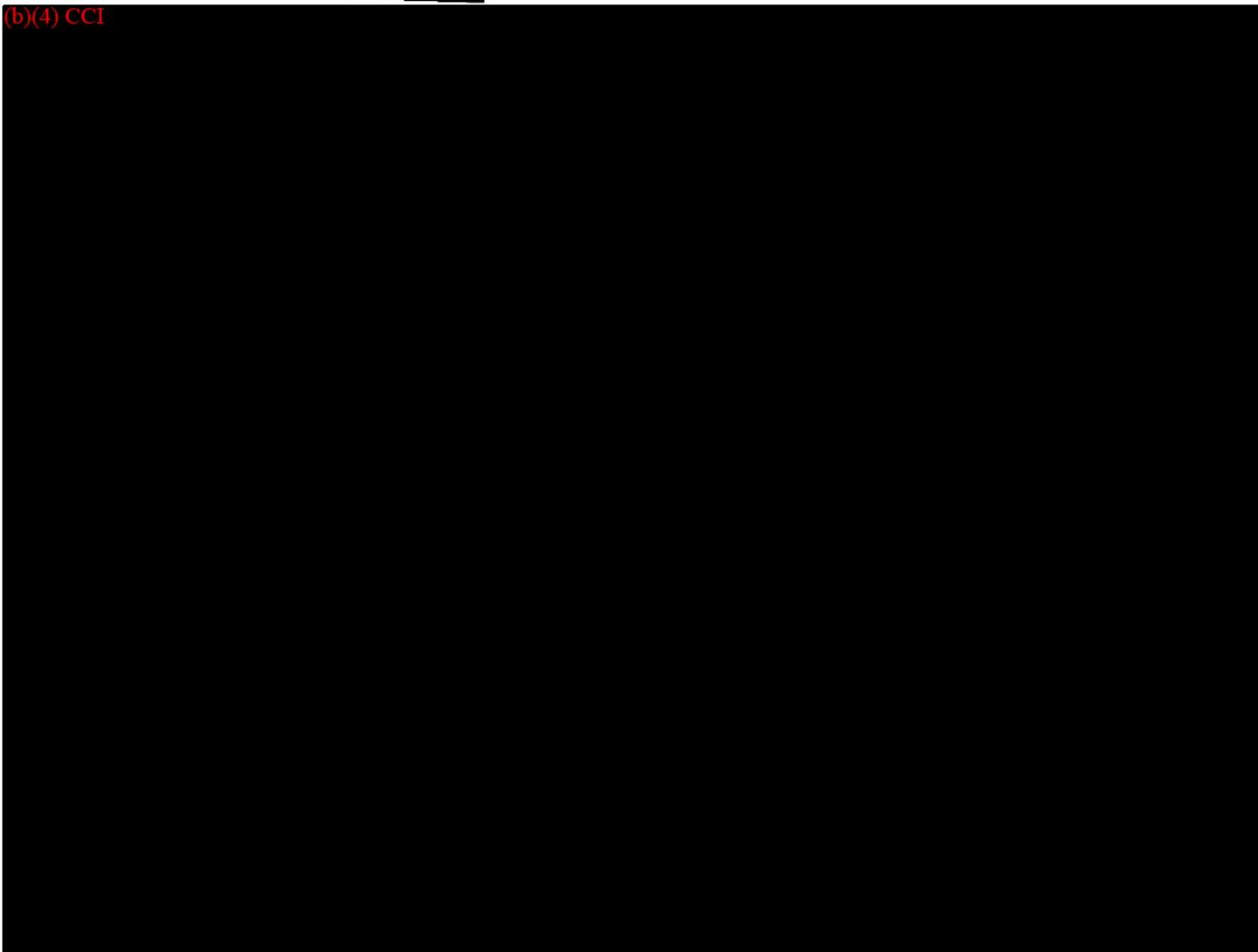
(b)(4) CCI



X. Performance Testing – Animal

XI. Performance Testing – Clinical

(b)(4) CCI



XII. Substantial Equivalence Discussion

	Yes	No
1. Same Indication Statement?		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision:

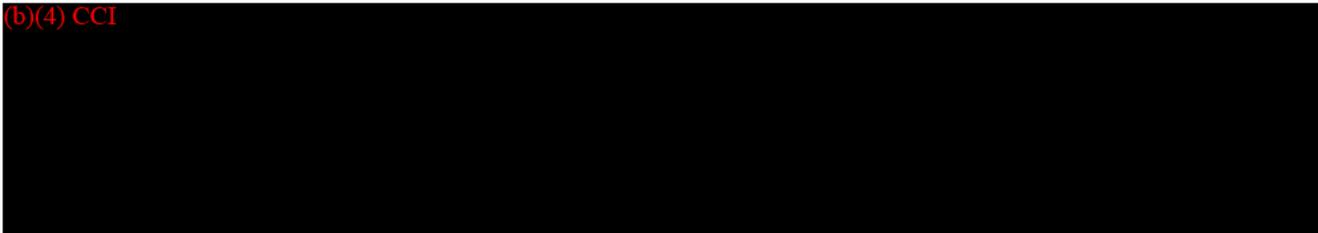
Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies

(b)(4) CCI



(b)(4) CCI



XIV. Contact History

XV. Recommendation

This file should remain on hold pending the deficiencies in the AI Letter.

Regulation Number:
Regulation Name:
Regulatory Class:
Product Code:

Karen S. Bray
Reviewer

10/20/08
Date

Branch Chief

Date

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):	YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)		
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/O_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?		
3. Does this device type require a PMA by regulation? (Please see management.)		
Questions 4-8 are intended to help you start your review:	YES	NO
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/O_4d69/Screening%20Checklist.doc)		
5. a. Did the firm request expedited review? (See management.) b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html)		
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:	
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:	
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html)		



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K082423

Date: September 24, 2008
To: The Record
From: Kareem S. Burney, M.S.

Office: ODE
Division: DGRND

510(k) Holder: Radiancy LTD
Device Name: No! No! Skin
Contact: Zvi Ladin
Phone: (781) 407-0900
Fax: (781) 407-0901
Email:

I. Purpose and Submission Summary

The 510(k) holder would like to introduce No! No! Skin into interstate commerce.

III. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, and Standards Form.

III. Device Description

Table with 4 columns: Question, Yes, No, N/A. Rows include questions about device life-supporting, implant status, software use, sterility, reusability, and cleaning instructions.

- This device is a portable 6 VDC battery-powered, hand-held device.
The treatment cycle delivers a series of broad spectrum light pulses to a single acne lesion.
The energy delivered to the lesion is a combination of focused light emitted from the halogen

92

lamp together with heat accumulated in the chamber placed over the acne lesion.

II. Indications for Use

No! No! Skin is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Sponsor should indicate that this device is for OTC use.

III. Predicate Device Comparison

- ClearTouch Light Unit Assembly by Radiancy Ltd (K032205)
- Zeno Acne Treatment System by Tyrell, Inc (K043377)
- ThermaClear Acne Treatment Device by DermaCare (K060653)

There are some differences between this device and the predicate device K043377 and K060653 use only heat to treat acne while K060411 uses both heat and light but is a prescription device. Between the comparison between this device and K060411, the wavelengths are different: This device has a wavelength range of 450 – 2000 nm and K060411 has a wavelength range of 430 – 1100 nm. The energy delivery duration is different between the two devices the current device has a duration of 10 sec and K060411 has a duration of 6 sec. The spot size is different but the max fluence is the same.

IV. Labeling

Device diagrams, box labels, instructions for use has been included in the submission.

The recommended treatment schedule is two sessions a day, 6-12 hours apart until the pimple heals. Threat only one pimple a time and treat each pimple twice per session. One treatment last 10 seconds and wait 5 seconds before treating the pimple a second time. (So each pimple will be treated for a total of 20 seconds).

V. Sterilization/Shelf Life/Reuse

This device is provided non sterile. Cleaning instructions has been included in the instruction for use.

(b)(4) CCI

VII. Software

Software is included in this device.

The sponsor needs to determine the level of concern and the documentation for that level of concern. That information can be found here: <http://www.fda.gov/cdrh/ode/guidance/337.html>.

Version:						
Level of Concern: Minor						
Software description:		<table border="1"> <tr> <th>Yes</th> <th>No</th> </tr> <tr> <td></td> <td></td> </tr> </table>	Yes	No		
Yes	No					
Device Hazard Analysis:						
Software Requirements Specifications:						

Architecture Design Chart:	
Design Specifications:	
Traceability Analysis/Matrix:	
Development:	
Verification & Validation Testing:	
Revision level history:	
Unresolved anomalies:	

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

(b)(4) CCI
[Redacted]

IX. Performance Testing – Bench

(b)(4) CCI
[Redacted]

X. Performance Testing – Animal

XI. Performance Testing – Clinical

(b)(4) CCI
[Redacted]

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XII. Substantial Equivalence Discussion

	Yes	No
1. Same Indication Statement?		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision:

Note: See

http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies

XIV. Contact History

XV. Recommendation

This file should be placed on hold pending the deficiencies in the AI Letter.

Regulation Number:
Regulation Name:
Regulatory Class:
Product Code:

Karen S. Boney
Reviewer
Neil I concur with AI.
Branch Chief

9/24/08
Date
9/24/08
Date

Date: September 24, 2008
To: Zvi Ladin
From: Kareem S. Burney, Biomedical Engineer

Subject: 510(k) from Radiancy for the No! No! Skin

Here are the outstanding questions on the submission.

1. In your submission, you provided the individual patient data for this device. However, because you are stating that your primary endpoint is time to improvement, we need to see this information clearly in your individual patient data. You provided lesion count and an improvement scale measure. We do not accept the improvement scale as being clinically meaningful. Please provide information showing how many lesions in your study made a one point change for each day based on the photographic lesion reference scale. This information should include all the lesions from both the placebo and active subjects. In addition, please provide information showing how many individuals showed overall improvement based on the photographic lesion evaluation in whom the majority of lesions showed this improvement.
2. In your submission, you did not indicate whether software is used with this device. If software is used with this device, then you should provide the level of concern of the software and the documentation necessary for the level of concern. Information about the level of concern and the documentation necessary can be found here: www.fda.gov/cdrh/ode/guidance/337.html.
3. In your indication for use page you did not indicate that this device is for Over The Counter use even though you state this in your submission. Please provide a revised indication for use page that indicates that this device is for over the counter use.

In your submission you explain that you want this device to be sold over the counter. Because you are requesting that your device is to be sold over the counter. Please address the following concerns we have about your instruction for use and usability study from K082423.

1. In your device description section, please describe more thoroughly in a section called, for example, "What is the no!no! skin?" Place this section first in the user manual.
2. The graphics now used in the "Meet..." section, "no!no! Skin...button." Remove the promotional phrase, "no stress...under control" because there was no measure of stress and the word control suggest the device is used as a preventive measure.

3. In the section, "The Pimple Problem", much of it is promotional. Please remove the promotional text, such as "based on LHE technology. . .world" which gives no useful information for lay persons. The text about green light, red light and heat does not seem to be directly related to this device, which appears to produce a broad spectrum of radiation not limited to red, green, and heat. Provide evidence for the statement, "Green. . .pore" or delete it. Provide evidence for the statement, "This begins . . .P.acnes" or delete it." Provide evidence for the statement, "Additional heat. . .swelling" or delete it.
4. Place a section citing the intended use of the device second immediately following the "What is the no!no! skin?" section. Incorporate the Acne Level Chart into it.
5. In the Acne Level Chart, move the second and third rows to be rows 1 and 2, respectively, since they are the kinds of acne this device treats. Change the column heading, "Is no!no! skin right for me?" to, for example, "Does no!no! skin treat this kind of acne?".
6. There is no section on contraindications. If there are any circumstances where the risk is known and exceeds the benefit of the device, place them in a contraindications section. The contraindications section follows immediately the section describing what the device is intended for. Contraindications should have all four parts of good warning statements as mentioned below to encourage compliance with them.
7. Separate the warnings from the precautions. Warnings are for issues where the adverse effect is serious injury or life threatening. Precautions are for issues where the adverse effect is mild or moderate or where the device may be damaged. Don't use "Danger" as a category of warning statements.
8. It is inappropriate for labeling for an OTC device cleared through the 510(k) process to tell a user to talk to their doctor before using the device. OTC devices are intended to be used by lay persons without their needing advice from a health care provider. OTC devices and their labeling should be sufficient to inform lay persons about them and their suitability. Thus, please remove the references to physicians in the first, second, and fourth cautions. Expand the second caution to include other sources of photosensitizers. The fifth caution seems unworkable because it contains the vague expression, "exposed to". Please clarify. The sixth caution about active implant needs to contain a more complete list of specific active implants that are problematic. Lay persons will not know how to logically determine what is meant by "active implant". In the seventh caution, explain how a lay person is supposed to determine whether they have these conditions. In the eighth caution, explain what is meant by personal use. In the ninth, tenth, eleventh, and twelfth cautions, if there is a danger from the light coming from the opening, the device likely needs an interlock that will prevent it from shining light when it

is not in firm contact with the skin. Please address this issue more fully. In the thirteenth, fourteenth, and fifteenth cautions, please address the issue of the device getting hot enough to burn and the need for a safety mechanism built into the device design to prevent its getting too hot.

9. There is no section on risks. Please create one and place it immediately after the Precautions section. The risk section should cite all known risks with the device, such as those inherent in the contraindications, warnings, and precautions.
10. Construct a 4-column table. For the table column headings, use, for example, Adverse Event, Likelihood of the Adverse Event, Adverse Effect, Likelihood of the Adverse Effect. Adverse Events are the things that may happen, such as overuse of the device in one area, the likelihood of this may be, for example, "unknown because it has not been tested". Or Adverse Events may be device malfunctions, such as a software or hardware failure.
11. Items in the Adverse Effects column are the results of the Adverse Events, for example, if there was an Event of software failure, the Effect might be the device might not turn off or might cause an exposure of greater intensity or duration. Or, Adverse Effects may be the signs and symptoms of the injurious Event and what remedial actions may be necessary. One of several corresponding "Adverse Effects" for this "overuse" may be, for example, "blistering of the skin" with its likelihood being, perhaps, "1 in every 10 persons" based on the clinical trial.
12. If this device was clinically tested, please give a brief summary of the study in lay language to help lay persons better understand its utility.
13. It is unclear what the difference in outcomes from treatments will be if the user deviates from the recommended treatment frequency (twice) and repeat frequency (every 6-12 hours) . For example, if a person treats the lesion 3 times or 1 time and then repeats the treatment every 4 hours instead of every 6-12 hours, please explain what the difference will be.
14. When the device starts to fail, please state whether it does so slowly or quickly and how a person can tell the device is failing. If, at some point the device appears to be working but is no longer emitting sufficient radiation for useful treatment, please state that.
15. Please include information pertinent to those who would take the device on international travel, such as problems with security or use with ACMains in other countries.
16. (b)(4) CCI


(b)(4) CCI [Redacted]

- a. (b)(4) CCI [Redacted]
- b. [Redacted]
- c. [Redacted]

17. (b)(4) CCI [Redacted]

18. (b)(4) CCI [Redacted]

19. Please include a toll-free telephone number where users may get more information if they need it.

20. Remove the user instructions, "Know Before . . .Skin" and integrate them if necessary into the "operating instructions" section. Remove the quick start guide. If there is a quick start guide, users may opt to use it instead of the more thorough user manual and may not see the important information pertaining to contraindications, warnings, precautions and risks before they use the device. There are several "warnings" and "precautions" in the "Operating Instructions". Some are erroneously labeled "Note" in the current version. Please write all statements that are warning and precautionary statements as Warnings and Precautions, or Cautions, and assure that they have all 4 parts of appropriate warnings statements as mentioned above .In the "Operating Instructions", revise the steps a lay person goes through to operate the device so that in each step, the first thing in the step is what the person does. Follow that in the step by what the device does in response and what the lay person may see or feel resulting from the device's activity. Label the steps "Step 1", "Step 2", etc to make them clearly steps.Consider dividing the "Operating Instructions" into "Set-Up", "Check-Out", and "Operating" sections since after set up, the device may be operated several times before it is set up again on another day. In the "Operating Instructions" where the user is told to do something, place a graphic showing a person doing that activity to enhance the instruction.Include in the "Operating Instructions" the directive to treat again after 6-12 hours.
21. In the "Cleaning Instructions" section, the texts suggest that more than one user may use the device. However, in the "Cautions" section, the device is said to be for personal use only. Please clarify whether more than one person may use the same device.The section on cleaning suggests one can prevent infection by following the steps outlined. Since the device is cleaned and not sterilized and there may be other things necessary to prevent infection, the text should probably say "reduce the risk of infection" instead. In this section there is a statement "Be sure the treatment. . .next use". This statement appears to be a precaution. Please write it as a Precaution with all 4 parts of a useful precaution.

Your submission is on hold pending your response with the requested information. You will receive a separate written notification that you have 30 days to respond to this request for additional information. If you need more than 30 days to provide a full and

complete response, you should submit a request for an extension of time to Document Mail Center (HFZ 401). For further information on how to apply for an extension and for general 510(k) information, please visit the FDA Website at:
http://www.fda.gov/cdrh/devadvice/31435.html#link_6

If you have any questions or need additional clarification, please contact me at (240) 276 - 3609.

Patient Labeling Review and Comments

Comments for CDRH internal use:

Document Number: K082423
Device Name: no!no! skin Acne Clearance System
Application Submitter: Radiancy
Description of Device: This device for treating mild to moderate inflammatory acne uses a low voltage halogen lamp to give broad spectrum light and heat (450-2000nm) to individual pimples and pustules at a fluence of 6J/cm². Each treatment cycle lasts 10s during which 20 light pulses of 100ms are emitted. The treatment spot is 8mm and covers an area of 0.5cm². Heat sources are both the residual heat from the device and direct heat IR radiation from the lamp. Each pimple or pustule is supposed to be treated with 1. 2 treatments with a 5s cool-down interval between them followed by 2. 2 similar treatments 6-12 hours later.
Labeling Reviewed and Commented On: User Comprehension Study April 3, 2008, User Manual, Exterior Package Labeling
Other Pertinent References:
Requestor: Kareem Burney, ODE/DGRND/GSDB
OCER/DDUPSA Reviewer(s): Jack McCracken
DDUPSA Approval: N/A
Review Due Date: September 18, 2008
Review Completion Date: September 15, 2008
Comments Sent To eRoom, Lead Reviewer, 'CDRH DUPSA-PL-REVIEW' (m/d/yy): September 15, 2008

Thank you for the opportunity to review this application and its patient labeling. I hope our comments are useful to you and the applicant. I have based my recommendations on our guidance document, <http://www.fda.gov/cdrh/ohip/guidance/1128.html>.

There is patient labeling in the application.

Because of the way a health care practitioner, patient, or caregiver will use this device, patients and caregivers can benefit from patient labeling. Therefore, we agree with the applicant that this device should have patient labeling.

I would like to review any proposed patient labeling the applicant sends you. Further, please send me the applicant's final printed labeling for this device whenever you receive it.

Comments for the applicant:

Essential

Device Description and Use

Please describe the device more thoroughly in a section called, for example, "What is the no!no! skin?" Place this section first in the user manual.

The graphic of the charger would be more useful if it were drawn with the same perspective as the perspective of the main unit.

Show the charger plug more closely associated with the charger socket to convey the idea that the two connect.

The graphics now used in the "Meet. . . ." section do not have legends properly located so they point to the correct device parts. Please revise the graphics so they correctly identify the device parts.

Remove the promotional information from the "Meet. . . ." section , "No!no! Skin. . .button." Remove the promotional phrase, "no stress. . .under control" because there was no measure of stress and the word control may suggest the device is used as a preventive measure.

Within this section describe briefly that the device produces light and heat that help heal acne.

Much of the text in the section "The Pimple Problem" is promotional. Please remove the promotional text, such as "based on LHE technology. . .world" which gives no useful information for lay persons. The text about green light, red light and heat does not seem to be directly related to this device, which appears to produce a broad spectrum of radiation not limited to red, green, and heat. Provide evidence for the statement, "Green. . .pore" or delete it. Provide evidence for the statement, "This begins . . .P.acnes" or delete it." Provide evidence for the statement, Additional heat. . .swelling" or delete it.

Information on Condition or Disease

Place a section citing the intended use of the device second immediately following the "What is the no!no! skin?" section. Incorporate the Acne Level Chart into it.

Improve the graphics in the Acne Level Chart so the graphics are clear and the scale of the images is shown.

In the Acne Level Chart, move the second and third rows to be rows 1 and 2, respectively, since they are the kinds of acne this device treats. Change the column heading, "Is no!no! skin right for me?" to, for example, "Does no!no! skin treat this kind of acne?"

Change the column heading, "Acne definition" to, for example, "What is this kind of acne?"

Contraindications

There is no section on contraindications. If there are any circumstances where the risk is known and exceeds the benefit of the device, place them in a contraindications section. The contraindications section follows immediately the section describing what the device is intended for. Contraindications should have all four parts of good warning statements as mentioned below to encourage compliance with them.

Warnings

Separate the warnings from the precautions.

Warnings are for issues where the adverse effect is serious injury or life threatening. Precautions are for issues where the adverse effect is mild or moderate or where the device may be damaged.

Don't use "Danger" as a category of warning statements.

All warning statements need to be complete. A complete warning statement has four elements. The four elements generally supported by research as necessary for an effective warning or precaution:

- a signal word (WARNING, CAUTION) to alert the reader that what follows is important hazard information. A symbol or icon may emphasize the effect of the signal word. Additional enhancement, such as bolding, larger type, underlining, italics, or color may help the information stand out from the rest of the text. However, studies have demonstrated that a large difference in font size between the signal word and the text may de-emphasize the importance of the text and therefore reduce the likelihood that the text will be read.
- a hazard avoidance directive in the form: "Do Not, Never, Avoid..." (or Do, if more appropriate) followed by the action to avoid (or perform). The objective of this directive is to give clear instructions to the user on how to avoid the hazard.
- a clear statement of the nature of the hazard associated with the warning (e.g., allergic reaction to material, strong magnetic field) or precaution (e.g., environmental effect, damage from resterilization) that characterizes the severity and the likelihood.
- the consequences, specifying the serious adverse events, potential safety hazards and limitations in device use that result if users do not follow instructions. The purpose is to give them a clear idea of the risk, which is likely to increase compliance. Hazard alert research has shown that this element has a significant effect on readers. If the consequences are not included, the alert is likely to be less effective.

In a group of warnings it may be permissible to include one action word for the group, depending on the context.

Some current warning statements are confusing or contain misspellings: "no!no!Skin. . .older", "Do not submerge . . .wert in anyway", "Keep inflammable away from inflammable. . .radiators"

Precautions

Some "Cautions" are confusing. Please reexamine your cautions to assure that they are reasonable.

It is inappropriate for labeling for an OTC device cleared through the 510(k) process to tell a user to talk to their doctor before using the device. OTC devices are intended to be used by lay persons without their needing advice from a health care provider. OTC devices and their labeling should be sufficient to inform lay persons about them and their suitability. Thus, please remove the references to physicians in the first, second, and fourth cautions.

Expand the second caution to include other sources of photosensitizers.

The fifth caution seems unworkable because it contains the vague expression, "exposed to". Please clarify.

The sixth caution about active implant needs to contain a more complete list of specific active implants that are problematic. Lay persons will not know how to logically determine what is meant by "active implant".

In the seventh caution, explain how a lay person is supposed to determine whether they have these conditions.

In the eighth caution, explain what is meant by personal use.

In the ninth, tenth, eleventh, and twelfth cautions, if there is a danger from the light coming from the opening, the device likely needs an interlock that will prevent it from shining light when it is not in firm contact with the skin. Please address this issue more fully.

In the thirteenth, fourteenth, and fifteenth cautions, please address the issue of the device getting hot enough to burn and the need for a safety mechanism built into the device design to prevent its getting too hot.

Risks

There is no section on risks. Please create one and place it immediately after the Precautions section. The risk section should cite all known risks with the device, such as those inherent in the contraindications, warnings, and precautions.

Construct a 4-column table. For the table column headings, use, for example, Adverse Event, Likelihood of the Adverse Event, Adverse Effect, Likelihood of the Adverse Effect. Adverse Events are the things that may happen, such as overuse of the device in one area, the likelihood of this may be, for example, "unknown because it has not been tested". Or Adverse Events may be device malfunctions, such as a software or hardware failure.

Items in the Adverse Effects column are the results of the Adverse Events, for example, if there was an Event of software failure, the Effect might be the device might not turn off or might cause an exposure of greater intensity or duration. Or, Adverse Effects may be the signs and symptoms of the injurious Event and what

remedial actions may be necessary. One of several corresponding "Adverse Effects" for this "overuse" may be, for example, "blistering of the skin" with its likelihood being, perhaps, "1 in every 10 persons" based on the clinical trial.

Interpreted Summary of Clinical Data

If this device was clinically tested, please give a brief summary of the study in lay language to help lay persons better understand its utility.

Need to Adhere to Care Regimen

It is unclear what the difference in outcomes from treatments will be if the user deviates from the recommended treatment frequency (twice) and repeat frequency (every 6-12 hours) . For example, if a person treats the lesion 3 times or 1 time and then repeats the treatment every 4 hours instead of every 6-12 hours, please explain what the difference will be.

Device Failure Time

Please state how long the device will last. Users would be interested in knowing how many treatments the device will be good for.

Device Failure Mode

When the device starts to fail, please state whether it does so slowly or quickly and how a person can tell the device is failing. If, at some point the device appears to be working but is no longer emitting sufficient radiation for useful treatment, please state that.

Travel and International Use

Please include information pertinent to those who would take the device on international travel, such as problems with security or use with ACMain in other countries.

User Testing Data

The application included a protocol and results of a study accomplished to examine the ability of users to comprehend use information and actually use the device. The device was a sham device.

- The objective of the study was to evaluate the ability of 40 literate people, male and female, ages 24 and older to understand the label instructions for deploying the device as described in the user guide without physician direction.
- The study listed as an additional endpoint a ". . . short written test . . . to judge [their] comprehension of the IFU and to determine any specific areas of information content that need emphasis. However, the 8 questions in the test pertained only to the device operation, namely:

- charging of the device
- the pressing of the treatment "on" button
- the meaning of the beeps
- how to stop the treatment
- how long the treatment takes
- what to do after the first treatment pass
- when to repeat treatment

There were deficiencies in the study design that make it difficult to conclude that lay persons buying this device OTC would be able to properly self select and use it.

- The objective tied to the primary endpoint was extremely limited in scope and did not appear to incorporate testing two important steps users go through as they make their decision to buy an OTC device:
 - selecting the device based on the external label of the OTC package:
 - their diagnosis of their condition
 - other information bearing on whether the device is right for them
 - comprehending the information on the intended use, contraindications, warnings, precautions, and risk information.
- In the diagnostic test, which is only part of selection process an OTC buyer would go through, there does not appear to be any information on the degree of agreement in diagnosis between the subjects, the evaluator, and the dermatologist. Table 3 cites the severities of acne diagnosed but not the extent of agreement.
- The application contained only summary data. The data for the individual subjects were not included in the application. Please include those data.
- The study screened out persons who would likely try to buy the device if it were available OTC. Because of this screening, any conclusions from this study seem not to be relevant to the OTC sale of the device.
 - The study was limited to "literate people". One inclusion criterion was "Read and comprehend English". Many in the OTC buying population are probably of low literacy in English. According to the protocol on page 13, "Participants will be asked a series of questions to confirm study eligibility" Please explain what these "questions" were and clarify the screening procedures you used so you gathered only "literate people" and excluded persons who could not "read and comprehend English". Please give more information on the persons who were screened out of the study and why they were screened out.
 - There was no obvious measure of the literacy of the subjects in the study. Please give more information on how you measured the literacy of the subjects and why the literacy of the subjects selected represented the literacy of the US OTC lay person population.
 - The study screened out 4 particular groups of subjects, e.g, pregnant women. Screening out these 4 groups prevented a test of the ability of the labeling to screen out these inappropriate users.
 - The recruiting advertisement listed some of inclusion/exclusion criteria and so it probably screened out some lay persons who would be eligible to buy the device OTC. Explain why screening out these persons does not make the results of the study invalid for an OTC device. State where the advertisement was placed and why that placement ensured that the typical OTC lay population would have accessed the advertisement.

- For the test that was given on comprehension, it :
 - may have been biased because in half the question/answer constructs the correct answer was the first of the three multiple choices
 - may not have tested the user manual, but rather the quick guide, which had most answers to the questions on it: 5 of the 8 questions are answered by the quick guide. The question on charging (question 1) was poorly answered and is an answer that was not on the quick guide.
 - may have been biased in the process of informed consent because the subjects read the informed consent form and were able to ask questions and receive answers before they got the labeling materials to read in preparation for the test on comprehension. The informed consent document gave some information on the procedure (answers to questions 2, 6). In the typical OTC situation, the labeling alone gives all the information a buyer needs and there is no one from whom a buyer can get answers to questions.
 - was administered under conditions that are unclear. Please clarify whether subjects were given Form C to fill out or staff asked the questions orally and filled out the form. Please clarify when subjects were given Appendix J. This appendix notes that the user is supposed to look at Appendix H and Appendix I, which was said to contain the user guide, to help with their assessment. Please clarify who filled out Appendix J. Appendix H appears to have a set of instructions given to subjects to follow. If Appendix H were given to subjects to follow, it probably further confused the assessment of the labeling since it also informs the users about device characteristics and usage. Please clarify whether Appendix H and Appendix I are identical to the Appendix H and Appendix I in pages 35-7 of the application.
- For the test on usability of the device:
 - The objective of the study was unclear, so it was unclear whether it was achieved. Please clarify the objective of the study and how meeting this objective was measured, given the apparently conflicting information in the application, e.g.,
 - According to page 11, the objective was to "understand the label instructions for deploying the . . . as described in the User's Guide". "Deploying" was defined as completing two tasks:
 - "Apply the . . .to a lesion on the skin (face area)"
 - "Trigger a series of pulses in accordance with the treatment instructions in the operator's manual."
 - Subjects, however, were asked to rate their degrees of success completing 7 tasks:
 - seeing if the device was charged
 - finding the device convenient to hold
 - ability to keep the device on the skin for the entire treatment sequence
 - finding the device convenient to apply
 - ability to hear the double beep
 - ability to trigger a sequence of light pulses
 - ability to repeat the procedure
 - Then, in "The Summary of the User Comprehension Study", page 6, there is the statement that Tables 4 and 5 summarize the overall success and success by task as assessed by the

users. It is unclear how these data were evaluated to form Table 4. It is not apparent that users were asked the question given in Table 4, "Were you able to complete all the tasks.?" Please clarify where the data in Table 4 originated.

- Table 5 summarized the responses for 7 "Tasks". However, only 4 of the tasks listed were really tasks (1,3,5,6), and only two of those (3, 6) were the tasks in the objective. The rest were statements on convenience or "could you repeat the procedure", which does not seem relevant.
- The text on page 7 stated that, according to evaluator reports, ". . .100% [of subjects] completed all essential tasks for device deployment" But it is unclear what these essential tasks were.

User Assistance Information

Please include a toll-free telephone number where users may get more information if they need it.

Operating Instructions

Remove the user instructions, "Know Before . . .Skin" and integrate them if necessary into the "operating instructions" section. Remove the quick start guide. If there is a quick start guide, users may opt to use it instead of the more thorough user manual and may not see the important information pertaining to contraindications, warnings, precautions and risks before they use the device.

There are several "warnings" and "precautions" in the "Operating Instructions". Some are erroneously labeled "Note" in the current version. Please write all statements that are warning and precautionary statements as Warnings and Precautions, or Cautions, and assure that they have all 4 parts of appropriate warnings statements as mentioned above .

In the "Operating Instructions", revise the steps a lay person goes through to operate the device so that in each step, the first thing in the step is what the person does. Follow that in the step by what the device does in response and what the lay person may see or feel resulting from the device's activity. Label the steps "Step 1", "Step 2", etc to make them clearly steps.

Consider dividing the "Operating Instructions" into "Set-Up", "Check-Out", and "Operating" sections since after set up, the device may be operated several times before it is set up again on another day.

In the "Operating Instructions" where the user is told to do something, place a graphic showing a person doing that activity to enhance the instruction.

Include in the "Operating Instructions" the directive to treat again after 6-12 hours.

Care and Cleaning Instructions

In the "Cleaning Instructions" section, the texts suggest that more than one user may use the device. However, in the "Cautions" section, the device is said to be for personal use only. Please clarify whether more than one person may use the same device.

The section on cleaning suggests one can prevent infection by following the steps outlined. Since the device is cleaned and not sterilized and there may be other things necessary to prevent infection, the text should probably say "reduce the risk of infection" instead.

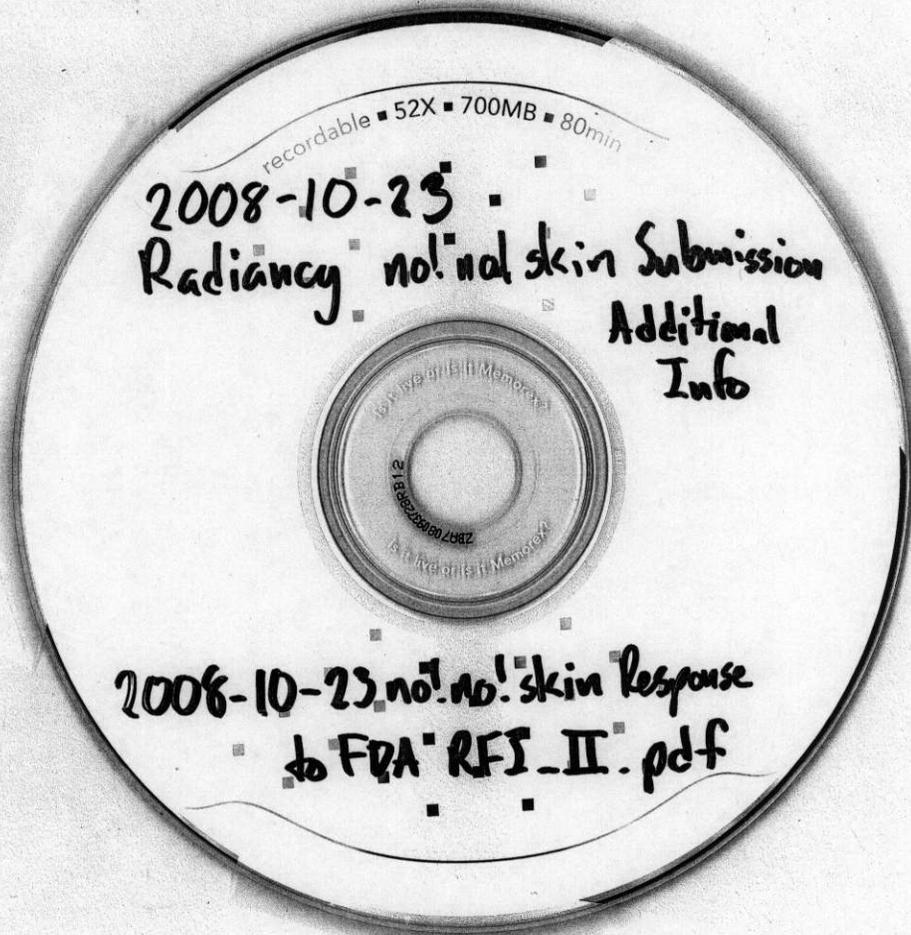
In this section there is a statement "Be sure the treatment. . .next use". This statement appears to be a precaution. Please write it as a Precaution with all 4 parts of a useful precaution.

Storage Instructions

If there are any special storage or disposal requirements, please state them.

Other Issue(s)

The external labeling for the device should contain at least all the indications for use, a brief description of the device, and the contraindications, warnings, precautions, and risks information. The current external label did not appear to have any of that information.





October 06, 2008

DR.

RADIANCY (ISRAEL) LTD.
C/O BOSTON MEDTECH ADVISORS
990 WASHINGTON ST.
DEDHAM, MASSACHUSETTS 02026
UNITED STATES
ATTN: ZVI LADIN

510k Number: K082423

Product: NO!NO! SKIN

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

K082423/51

October 2, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA CDRH DMC

OCT 6 2008

Received

K-23

Attn.: Mr. Kareem S. Burney

Re: 510(k) #K082423 – no!no! Skin™ Device

Dear Mr. Burney:

In response to FDA's request for additional information, dated September 25, 2008, the sponsor – Radiancy (Israel), Ltd. has provided the attached documents. This letter summarizes the detailed response to all the questions raised by the agency, providing first the question (*italicized*), followed by the answer.

The following appendices are attached to this response:

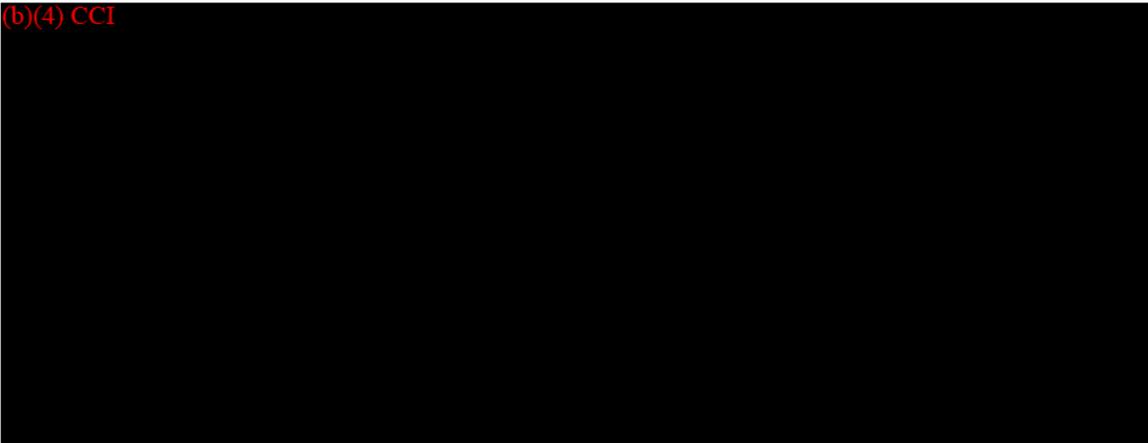
1. Appendix I – Statistical Summary (addendum to Appendix 20-F in original submission)
2. Appendix II – Revised Indications for Use Form
3. Appendix III – Risk Analysis for Eye Safety
4. Appendix IV – Revised User Manual

Please refer any communications regarding this application to: Zvi Ladin, Ph.D, Boston MedTech Advisors, Inc. 990 Washington Street, Suite 204, Dedham, MA 02026, Ph: (781) 407-0900 / x104, FAX: (781) 407-0901, Cell: (617) 921-6400, E-mail: zladin@bmtadvisors.com.

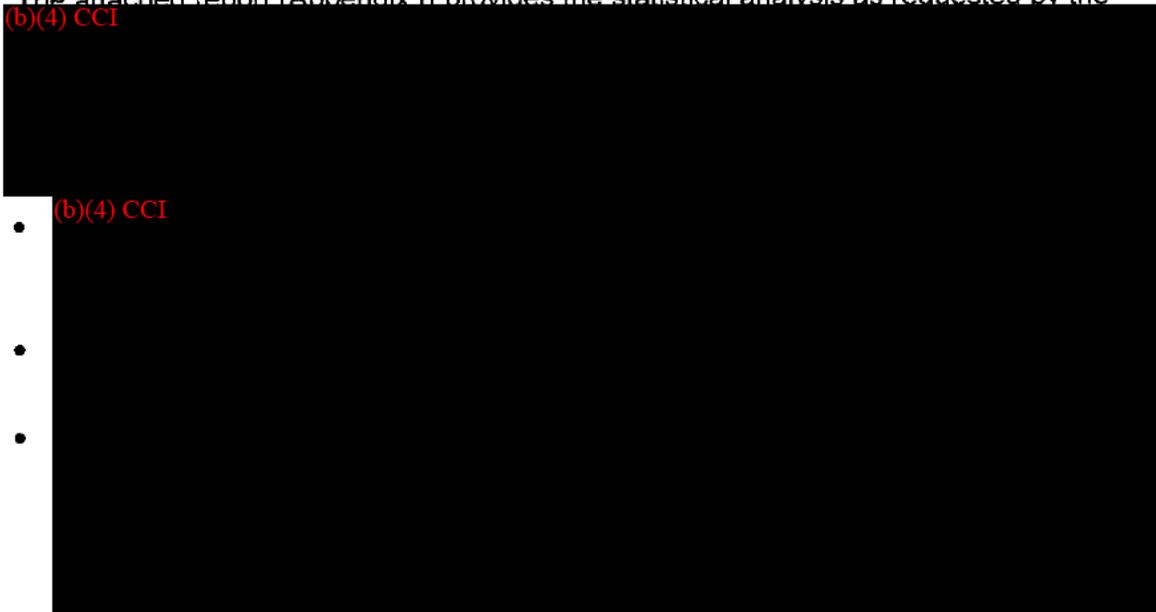
Sincerely yours,



Zvi Ladin, PhD, Principal, Boston MedTech Advisors, Inc., for
Dolev Rafaeli, CEO, Radiancy, Inc.

I. (b)(4) CCI


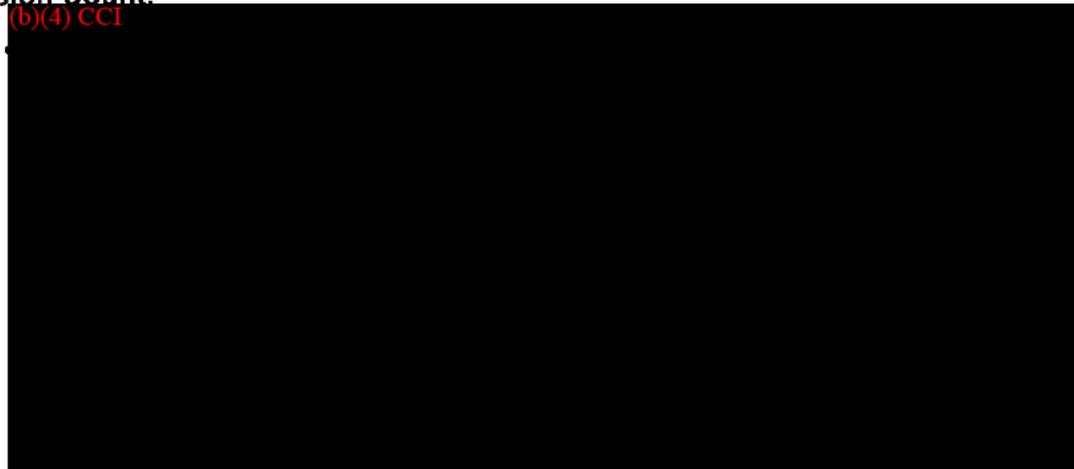
The attached report (Appendix I) provides the statistical analysis as requested by the (b)(4) CCI

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-

Section I of this report analyzes the clinical data based on a count of lesions, while Section II is based on the count of patients:

- **Lesion Count:**

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(b)(4) CCI

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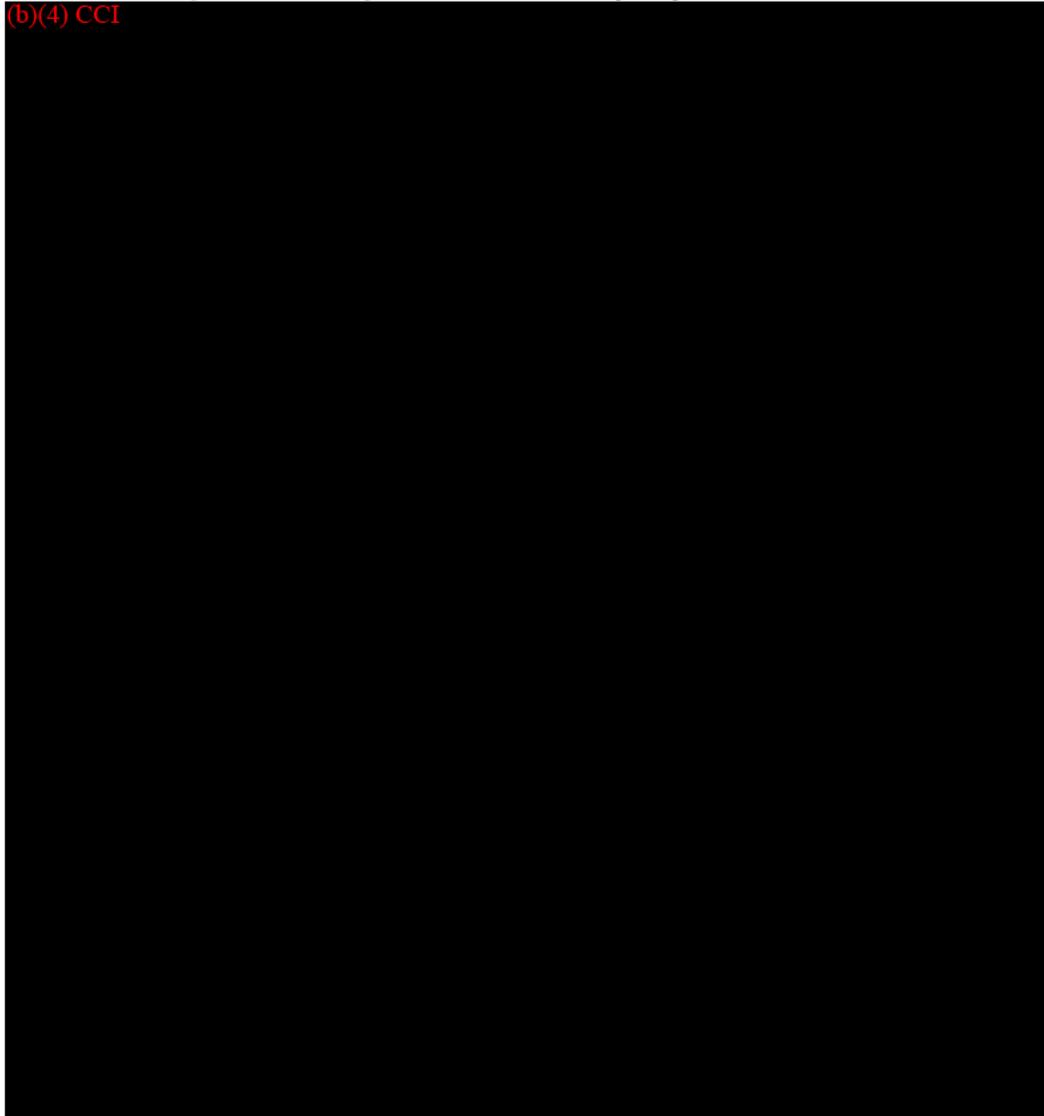
- **Patient Count – Improvement by a One Unit in Majority of Lesions**

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In conclusion, (b)(4) CCI [Redacted]

- (b)(4) CCI [Redacted]
- [Redacted]

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(b)(4) CCI [Redacted]

3. (b)(4) CCI [Redacted]

STATISTICAL SUMMARY

RADIANCY INC.—SUMMARY OF THE *NO!NO!*
*SKIN*TM ACNE CLEARANCE SYSTEM
PIVOTAL CLINICAL STUDY

(b)(4) Clinical Study

(b)(4) Clinical Study



Indications for Use

510(k) Number (if known):

Device Name: no!no! Skin™

Indications For Use: no!no! Skin™ is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _____

31 December 2007

Eye Safety risk Analysis for NO!NO!-Skin

Introduction

NO!NO!-Skin is a battery operated skin treatment device with a Tungsten/Halogen lamp light as a source of energy.

The Tungsten/Halogen lamp is a Non-coherent wide band, wide angle light source. Exposure limit values for non-coherent radiation were taken from DIRECTIVE 2006/25/EC, regarding with the minimum health and safety requirements regarding the exposure of workers to risks arising from artificial optical radiation.

Intensity Data of the Light Source

1. Output power = 0.6W/cm²
2. Spectrum: 480 – 2000 nm
3. Fluence: 6 J/cm²
4. Maximum Pulse duration: 200msec.
5. Number of pulses per treatment: 20
6. Treatment time: 10sec.

Criteria A – Photoretinitis of the Eye Retina

(Wavelength 300 – 700nm)

Exposure limit value $L_b = 10^6/t$ for:

$t < 10,000$ sec.

$\alpha > 11$ mrad

$t_{\text{pulse}} = 0.2$ sec.

$t_{\text{Treatment}} = 4$ sec.

$L_{b(\text{pulse})} = 5,000$ W/cm²

$L_{b(\text{treatment})} = 250$ W/cm²

Criteria B – Retinal Burn of the Eye Retina

(Wavelength 380 – 1400nm)

Exposure limit value $L_r = 5 \times 10^7 / C_{\alpha} t^{0.25}$ for:

$10 \mu\text{sec} < t < 10 \text{ sec.}$

$C_{\alpha} = 100$ for $\alpha > 100 \text{ mrad}$

$t_{\text{pulse}} = 0.2 \text{ sec.}$

$t_{\text{Treatment}} = 4 \text{ sec.}$

$L_{\text{b(pulse)}} = 334 \text{ W/cm}^2$

$L_{\text{b(treatment)}} = 707 \text{ W/cm}^2$

Criteria C – Corneal Burn Cataractogenesis of the Eye Cornea Lens

(Wavelength 780 – 3000nm)

Exposure limit value $E_{\text{IR}} = 18,000 t^{-0.75}$ for:

$t < 1,000 \text{ sec.}$

$t_{\text{pulse}} = 0.2 \text{ sec.}$

$t_{\text{Treatment}} = 4 \text{ sec.}$

$E_{\text{IR(pulse)}} = 60 \text{ W/cm}^2$

$E_{\text{IR(treatment)}} = 6.4 \text{ W/cm}^2$

Findings:

1. Even under the assumption that all the radiation is within a given criteria, the exposure of all NO!NO!-Skin lamp is substantially lower than limits.
2. Even under the assumption that all the 20 pulses one continuous pulse, the exposure of all NO!NO!-Skin lamp is substantially lower than limits.

Conclusions:

The exposure level of the NO!NO!-Skin lamp is substantially lower than the limit in the specified in DIRECTIVE 2006/25/EC for artificial Non-coherent light sources.

User Manual
Instructions for Use & Technical Description
Professional acne treatment for personal use

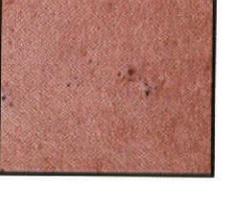
Index

Index	2
What is no!no! Skin	3
Contraindications	5
Warnings	5
Precautions	5
Benefits & Risks	6
How to use no!no! Skin	8
Charging the no!no! Skin	10
Cleaning Instructions	10
Troubleshooting	11
Product Labels	12
Technical Specifications	13

What is no!no! Skin

no!no! skin™, is a small handheld device intended for the treatment of individual pimples. The no!no! Skin™ treatment delivers a flash of light and heat to the pimple. Treatments last 10 seconds and need to be performed twice a day. The patented treatment tip provides therapeutic light and heat to the body and can be used on the face, arms, back, and chest. Simply put the treatment tip over your pimple and push the button. The treatment accelerates the healing process and pimples clear in half the time.

Who should use no!no! Skin

Acne type		Acne definition	Does no!no! skin treat this kind of acne?
Moderate acne		Many papules & pustules (with pus) with inflammation	Yes
Mild acne		Several papules (pimples) with inflammation	Yes
Severe acne		Inflamed papules and pustules with several deep nodular and cystic lesions (hard knots under the skin)	No
Comedonal acne		Blackheads and whiteheads with slight inflammation (red)	No

Clinically Proven

The no!no! Skin Device was tested in a clinical trial in comparison to a placebo (mock) device. In the trial participants that were not aware the kind of device they have received (active/ placebo) treated 4 pimples they have chosen on their faces for 4 days. The results showed that lesions treated by the active device started clearing earlier than half the time compared to pimples treated by the placebo. Studies show that no!no! Skin works best at the first sign of pimples, but will clear mature pimples as well.

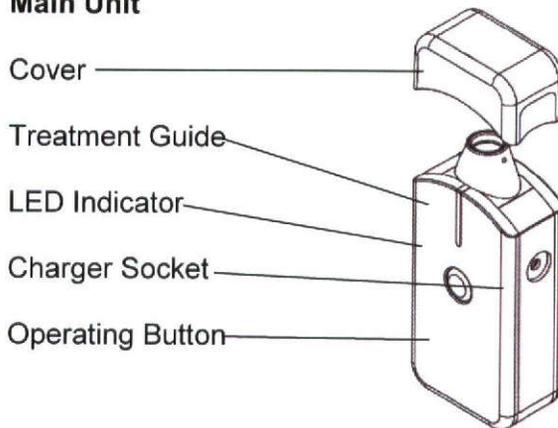
How does it Work?

no!no! Skin uses an adapted form of Light & Heat Energy technology, LHE. LHE is proven to treat acne by combining light with a direct heat process that accelerates the healing process

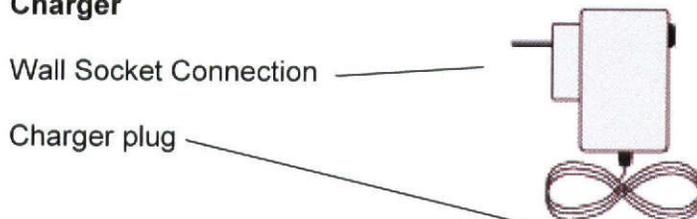
Know your no!no! Skin

Below is a diagram of no!no! Skin and its parts. It is important to know these parts for the proper use and care of no!no! Skin.

Main Unit



Charger



Contraindications

Do not use no!no! Skin:

- if you have epilepsy.
- if you are pregnant or nursing.
- on lesions such as moles, warts, ingrown hairs, insect, spider bites or stings, infected areas, open sores or wounds
- if your skin is sensitive to heat or light because no!no! Skin uses light and heat and these may affect your skin.

Warnings

- Use no!no! Skin for its intended use as described in this manual.
- Do not use no!no! Skin if you are taking prescription medication for the treatment of your acne. Please consult your medical professional if you are on prescription medication
- If you have an unexpected reaction (refer to section XX), please stop using no!no! Skin and contact your health care professional.
- no!no! Skin may be used by the ages 14 years and older.

Precautions

- Treat only areas that are currently affected by acne.
- Treat each pimple individually.
- If at any time during the treatment tip feels too hot, remove it and press the button to end the treatment.
- Keep no!no! Skin and the charging unit away from water
- Do not use no!no! Skin if it has fallen into water.
- Do not use no!no! Skin if bathing or standing in water
- Always unplug no!no! Skin from its charger before use, cleaning or maintenance.
- Do not use no!no! Skin or the charger if their cases are damaged in anyway,
- Use no!no! Skin with its original charger.
- Keep away from inflammable environments and hot surfaces such as stoves and radiators.
- Do not open the outer casing of no!no! Skin. This will void your warranty and may damage the unit.
- Do not drop or bump the no!no! Skin as this may cause internal damage to the unit.

Benefits & Risks

You can use no!no! Skin for the treatment of individual acne pimples. no!no! Skin is a handheld medical device that gives a precise dose of heat and light to each individual acne pimple. It accelerates the healing process of the pimple, improving the appearance and lessening the chances of scarring

Our clinical trials indicated no major adverse effects. Side-effects that may occur include brief discomfort due to the heated pulse, redness or dryness. You may see redness where the tip is applied and this should quickly fade away. If you notice any other side effects that were not mentioned above, we recommend you stop using no!no! Skin and contact your medical professional for advice.

CLINICAL ADVERSE EVENTS				
Adverse Event	Likelihood of Adverse Event	Adverse Effect	Likelihood of Adverse Effect	
Regular Use of Unit	Expected	Discomfort (burning sensation)	Rare (1 in 30 clinical study participants experienced discomfort)	
		Skin irritation	Very Rare	
Shared Use of Unit	Unexpected	Skin Infection	Rare	
Mechanical Adverse Events				
Adverse Event	Likelihood of Adverse Event	Adverse Effect		Likelihood of Adverse Event
		Serious	Minor	
Electronic Failure	Unexpected	Lamp operates continuously and causes overheating		Rare
Electronic Failure	Unexpected		Lamp operates at Higher Voltage and Current and causes overheating	Rare

How to use no!no! Skin

Get Ready to no!no! Skin

Before using no!no! Skin there are a few things that will help make the treatment more comfortable and effective. We advise you to test no!no! Skin on your arm before to become familiar with the pulsing sensation. And make sure your skin is clean and dry before using no!no! Skin. To make sure you are treating only one pimple at a time, especially in hard to see areas, use a mirror.

Set-up

- Charge no!no! Skin overnight before using it for the first time.
- Recharge no!no! Skin after each use until the orange light stops blinking and the green light turns on.
- Before beginning treatment, unplug the charger from the electrical outlet and disconnect the no!no! Skin.

Operation

Step 1		Remove the cover.
Step 2		Line the Treatment Guide up with the pimple and place no!no! Skin on the pimple and in full contact with your skin. Refer to the chapter titled "Meet no!no! Skin" to see the where the Treatment Guide is.
Step 3		Push the button. A single beep will sound to signal the start of treatment.

Step 4		Keep no!no! Skin in full contact with the pimple for 10 seconds.
Step 5		Remove no!no! Skin after you hear 2 beeps.
Step 6		Wait 5 seconds and treat the same pimple again.

Remember:

- One treatment lasts 10 seconds.
- A single beep will sound to signal the start of treatment.
- A light will flash for the duration of the treatment.
- A double beep will sound to signal the end of treatment.
- Treat each pimple twice a day until the pimple heals. Each session should be 6-12 hours apart.
- Treat each pimple twice a session

KEEP THESE OPERATING INSTRUCTIONS FOR FUTURE REFERENCE.

If you have any questions, please call toll free: 1 888-380-0030

Charging the no!no! Skin

Charge **no!no! Skin** overnight before using it for the first time.

Recharge **no!no! Skin** after each use until the orange light stops blinking and the green light appears.

For safety reasons, your **no!no! Skin** will not operate while plugged into the charger.

Please refer to the table below to understand the different meanings of the LED Indicator located at the bottom of the Treatment Guide.

LED Indicator	Meaning	Course of action
Blinking Orange	Charging	
Steady Green	Fully charged	
3 Long Beeps	Low battery	Need to charge, but can still operate
Steady Orange for 10 seconds	Very low battery	Charge immediately, will not work

Cleaning Instructions

In order to prevent infection, thoroughly clean the **no!no! Skin** treatment tip before and after each use. Dip a clean piece of gauze or cloth into rubbing alcohol and gently wipe the treatment tip. Be sure the treatment tip is completely dry before the next use.

Troubleshooting

no!no! Skin was designed to give you a trouble-free method to deal with acne. However, from time to time, problems may appear.

What do I do if...

my no!no! Skin does not emit a pulse?

Check the power indicator to make sure your **no!no! Skin** has been fully charged.

Recharge the unit.

I've charged my no!no! Skin, but the power indicator remains at low and it won't emit a pulse?

Check the charger's power cord and plugs for damage. Try another outlet, the one you were using may not be working properly.

If a problems persists, or one that is not mentioned occurs, contact a no!no! Skin service center

I want to travel to another country?

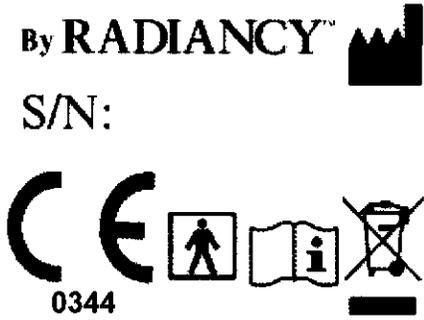
no!no! Skin can be used in any country. The only thing you need is a plug adaptor that will fit the outlet of the country you are going to. If you are flying, we suggest packing it in your suitcase to avoid possible security issues

Product Labels

This section describes the labels affixed to the no!no! Skin. It is recommended that users review the meaning of these labels for everyday usage, and in case any details are needed for service.

The table below briefly reviews a number of the internationally recognized symbols that are found on the no!no! Skin main unit and its external package.

This sticker is found on the device.

Label	Location and Comments
	<p>Located at the bottom of the device.</p> <p>This label includes manufacturer details, Standard International Symbols and the system's Lot number.</p>

Standard International Symbols

Symbol	Meaning
	Degree of protection against electric shock: Type BF applied part
	CE mark presents the compliance to the European Medical Device Directive 93/42/EEC, Class IIa device. The number (0344) is of the certifying body, KEMA Notified Body
	The symbol on the label affixed to this device means "Attention, consult accompanying documents".
	Manufacturer
	Protect the environment by not disposing of this product with household Waste (2002/96/EC). Check your local authority for recycling advice and facilities (Europe only).

Technical Specifications

Light Source.....Halogen Lamp with Light & Heat Energy (LHE)

Wavelength Range.....480 – 2000 nm

Fluence.....6J/cm²

Pulse Train.....20 pulses per application

Treatment Area.....0.5 cm²

Treatment Time.....10 seconds

Classification..... Internally Powered Equipment, Type BF

Mode of Operation.....Short-time Operation

Operating Conditions.....Ambient Temperature: +5°-35°

Electrical Requirements for Battery Charger.....Electrical Input Voltage 100 – 240VAC
at 50/60Hz.

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no!no! Skin User Manual, Revision 04, July 2008 Part Number: 2018590.

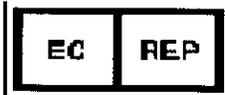
Note: The information in this document is confidential and proprietary. It is provided to customers and authorized representatives of Radiancy only. The content of this manual is furnished for informational use only, is subject to change without notice, and should not be construed as a commitment by Radiancy Inc.

LHE[®] is a registered trademark, and Radiancy[™] and no!no! are trademarks of Radiancy in the United States and in other countries.

The Quality Management System of Radiancy complies with the Quality Management Standard ISO 13485:2003.



Manufacturer: Radiancy (Israel) Ltd., 9 Gan-Rave St., P.O. Box 13111, Industrial Park, Yavne 81223, Israel, Tel: 972-8-943-3100, Fax: 972-8-943-8020. www.radiancy.com



European Representative: Obelis S.A, Av. de Tervuren 34 Bte .44, B-1040 Brussels, Belgium: Tel: 32 (0) 2 732 5954, Fax: 32 (0) 2 732 6003, GSM 07545 4660, e-mail: obelis@info.be



The CE mark presents the compliance to the European Medical Device Directive 93/42/EEC, Class IIa device. The number (0344) is of the certifying body KEMA Notified Body.

2018590 / Rev 03 / May 2008



October 24, 2008

DR.

RADIANCY (ISRAEL) LTD.
C/O BOSTON MEDTECH ADVISORS
990 WASHINGTON ST.
DEDHAM, MASSACHUSETTS 02026
UNITED STATES
ATTN: ZVI LADIN

510k Number: K082423

Product: NO!NO! SKIN

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

1082423 / 52

October 23, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA CDRH DMK

OCT 24 2008

Received

Attn.: Mr. Kareem S. Burney

Re: 510(k) #K082423 – no!no! Skin™ Device – Response to FDA's Request for
Additional Information Dated October 21, 2008

Dear Mr. Burney:

In response to FDA's request for additional information, dated October 21, 2008, the sponsor – Radiancy (Israel), Ltd. has provided the attached document. This letter summarizes the detailed response to FDA's request for clinical results documenting a statistically significant difference in the time to resolution between lesions treated by the active and placebo devices.

Please refer any communications regarding this application to: Zvi Ladin, Ph.D, Boston MedTech Advisors, Inc. 990 Washington Street, Suite 204, Dedham, MA 02026, Ph: (781) 407-0900 / x104, FAX: (781) 407-0901, Cell: (617) 921-6400, E-mail: zladin@bmtadvisors.com.

Sincerely yours,

Zvi Ladin

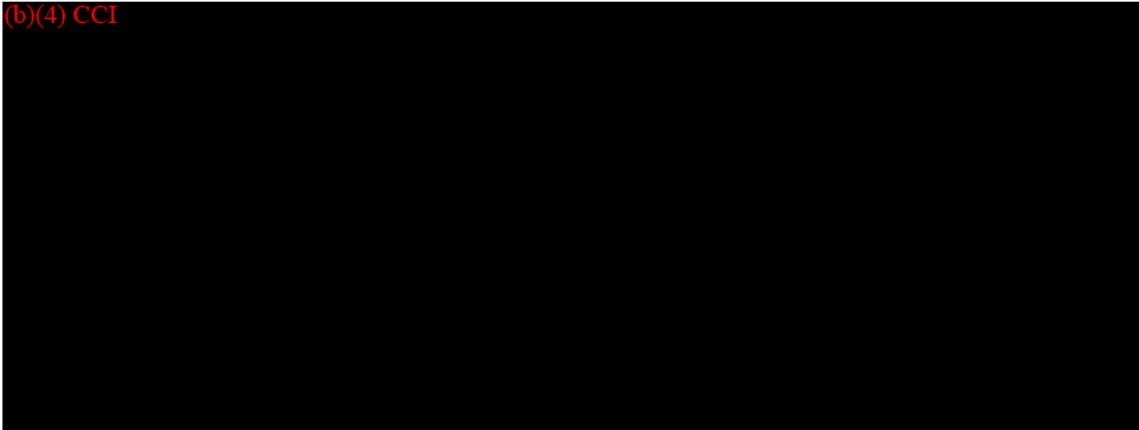
Zvi Ladin, PhD, Principal, Boston MedTech Advisors, Inc., for
Dolev Rafaeli, CEO, Radiancy, Inc.

K29

FDA's Request for Additional Information:

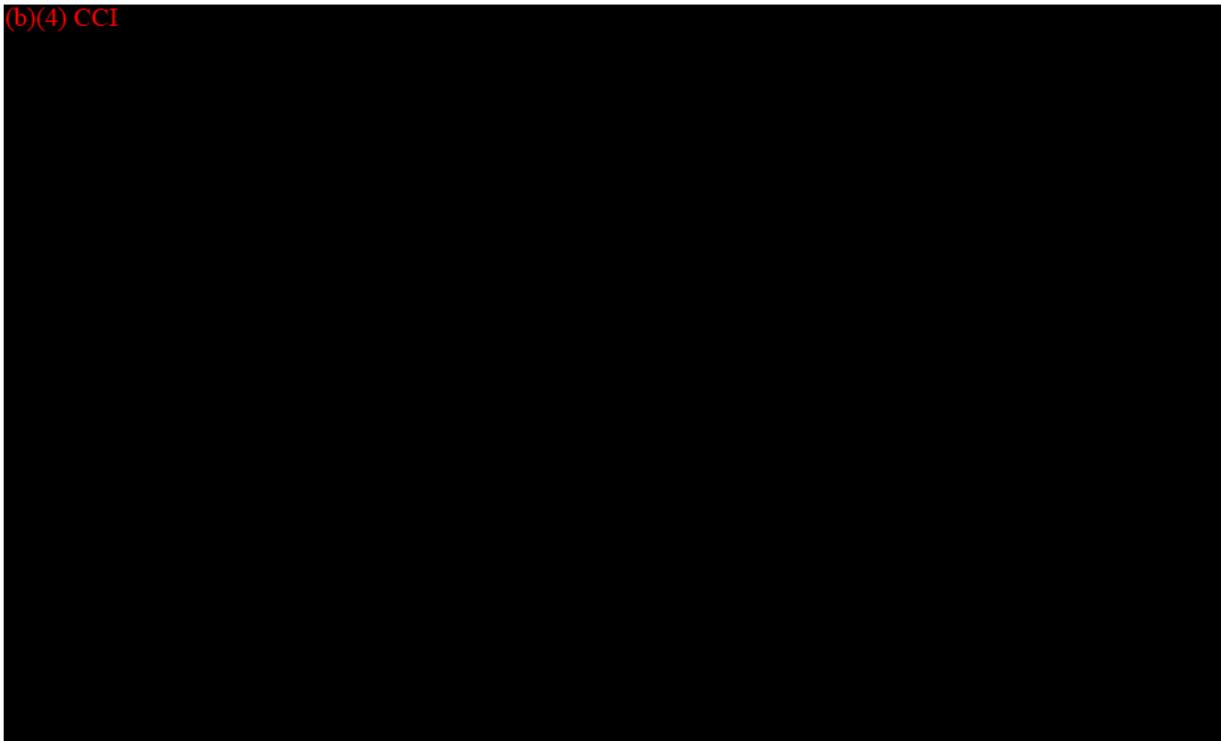
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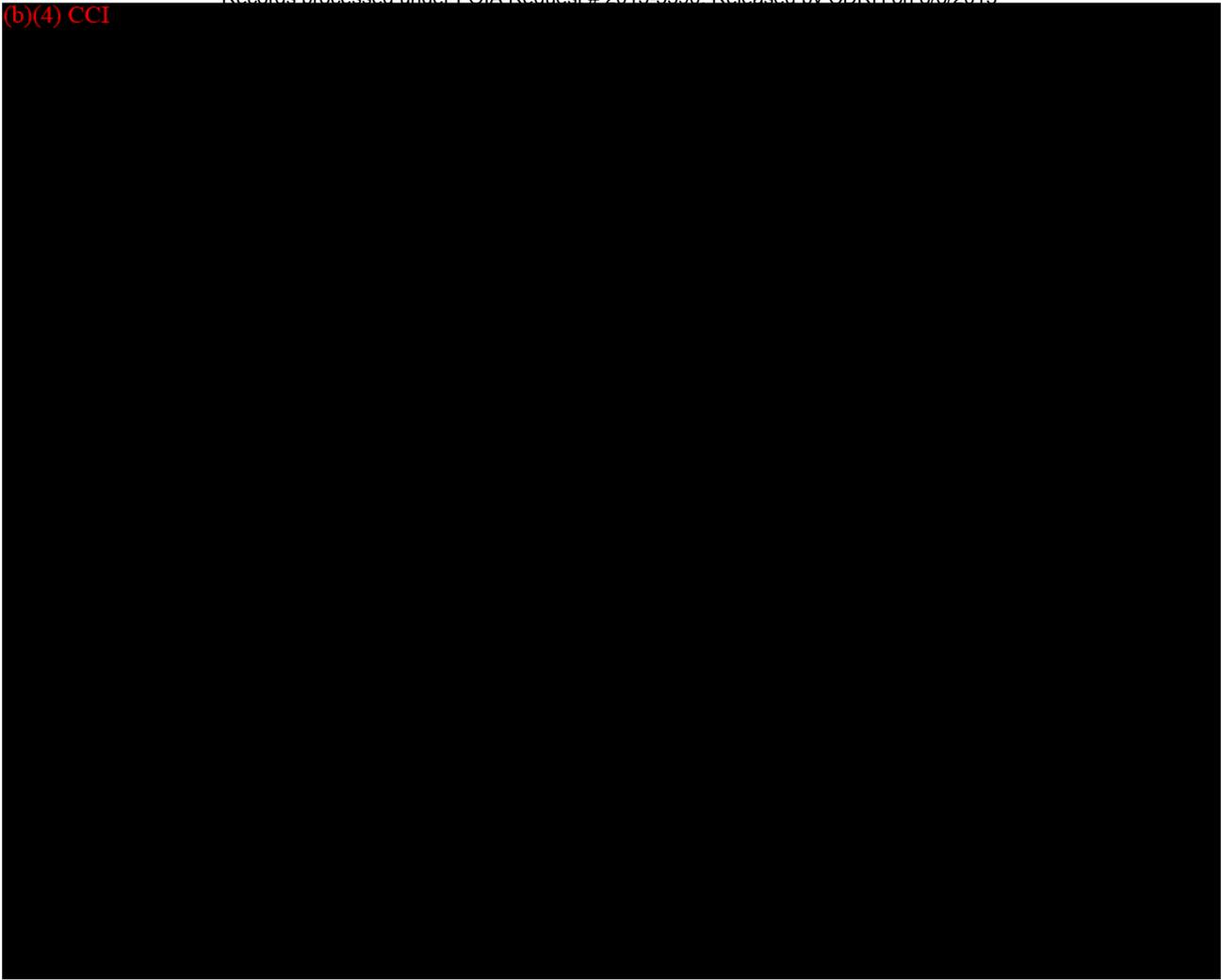


Radiancy's Response:

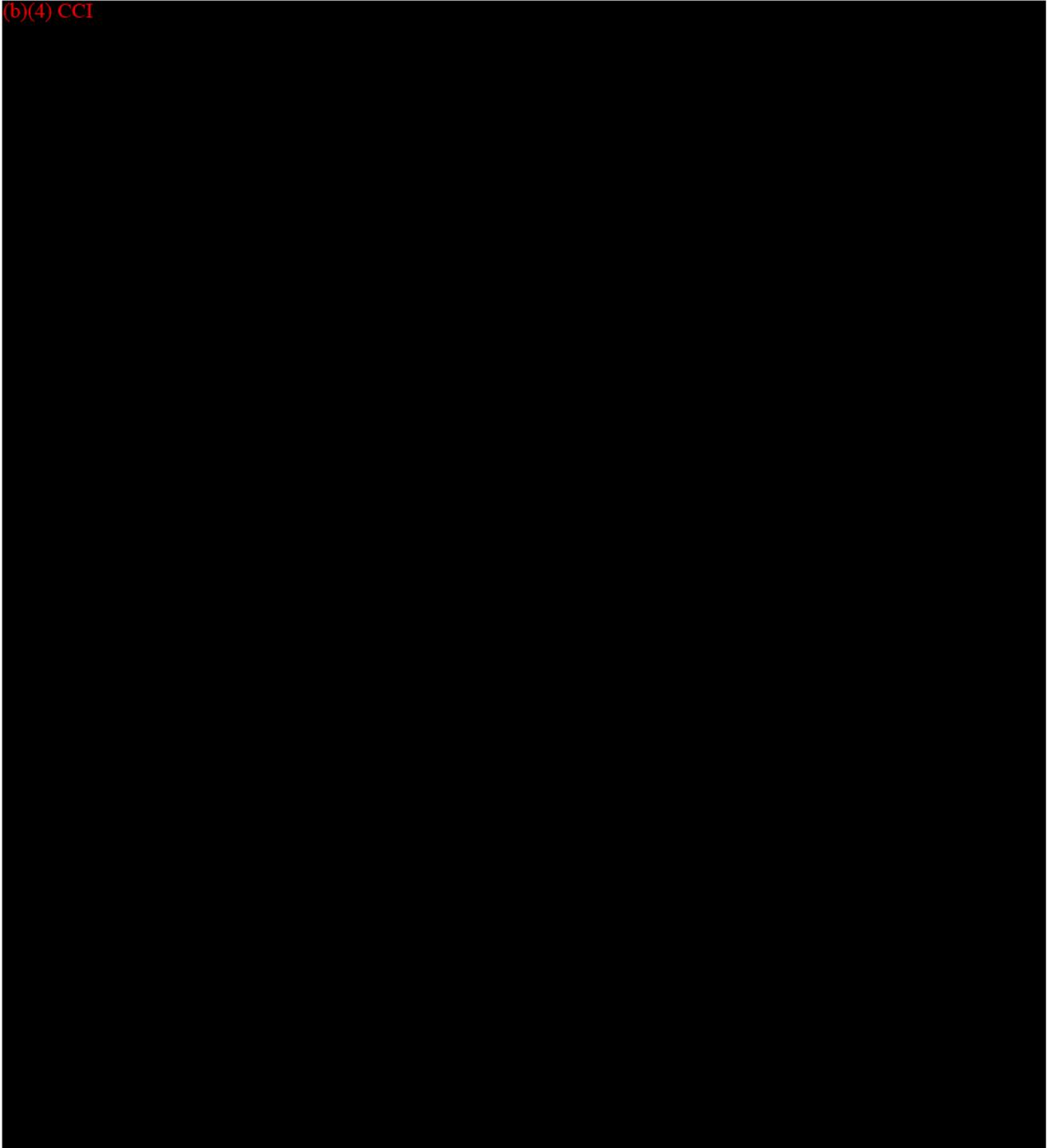
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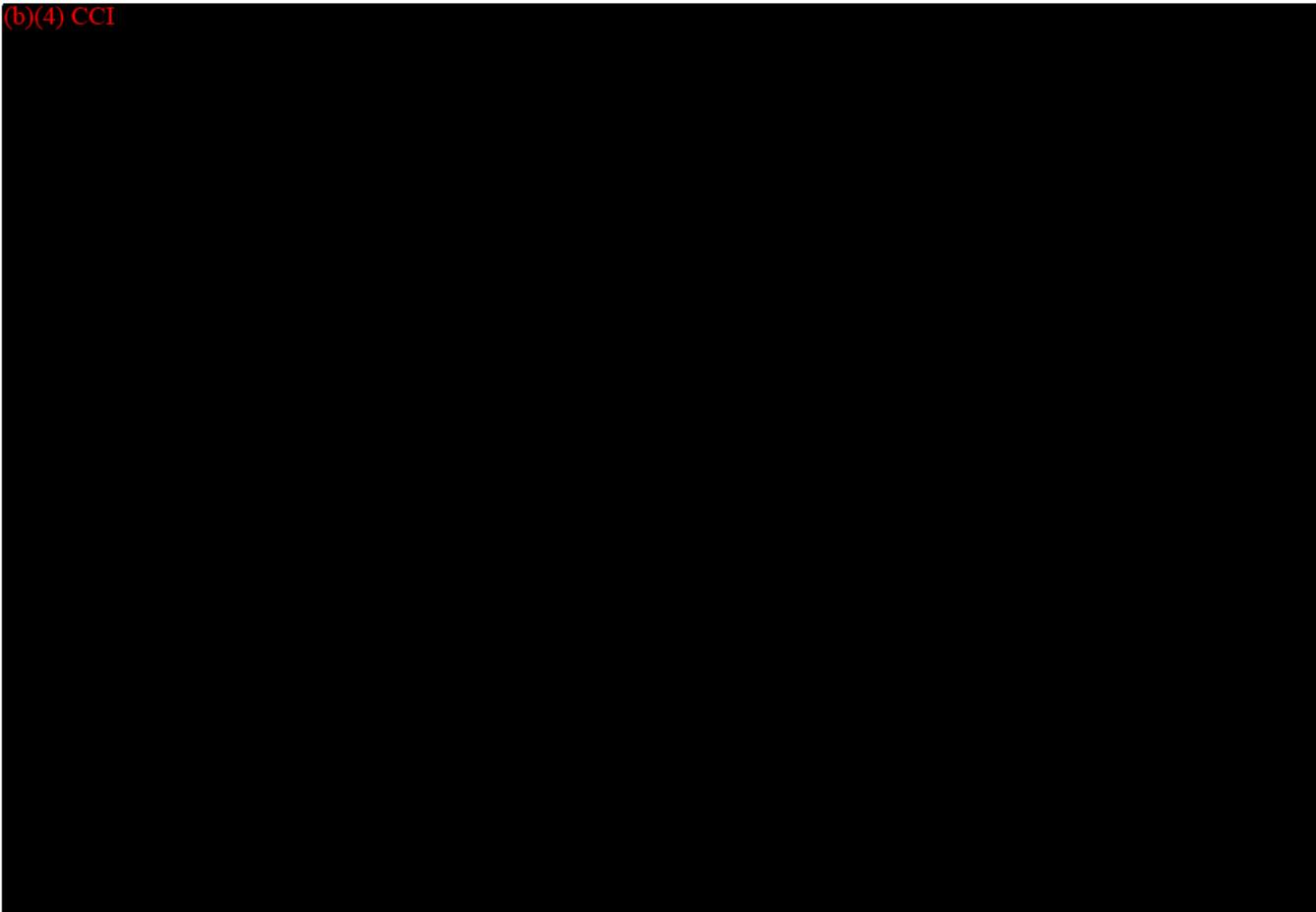
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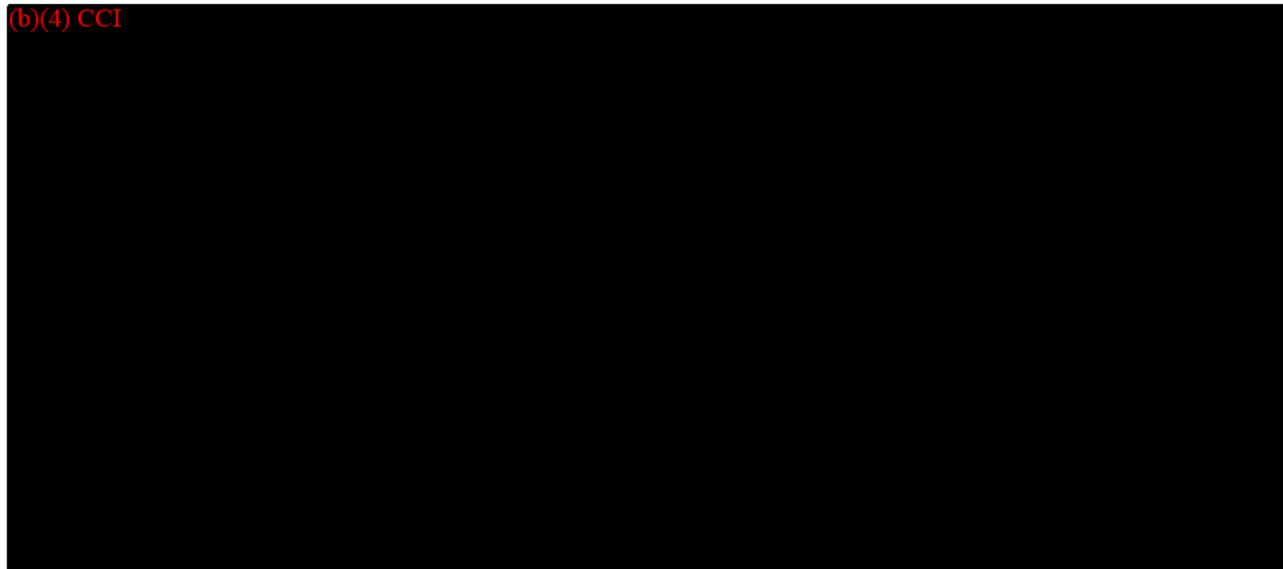
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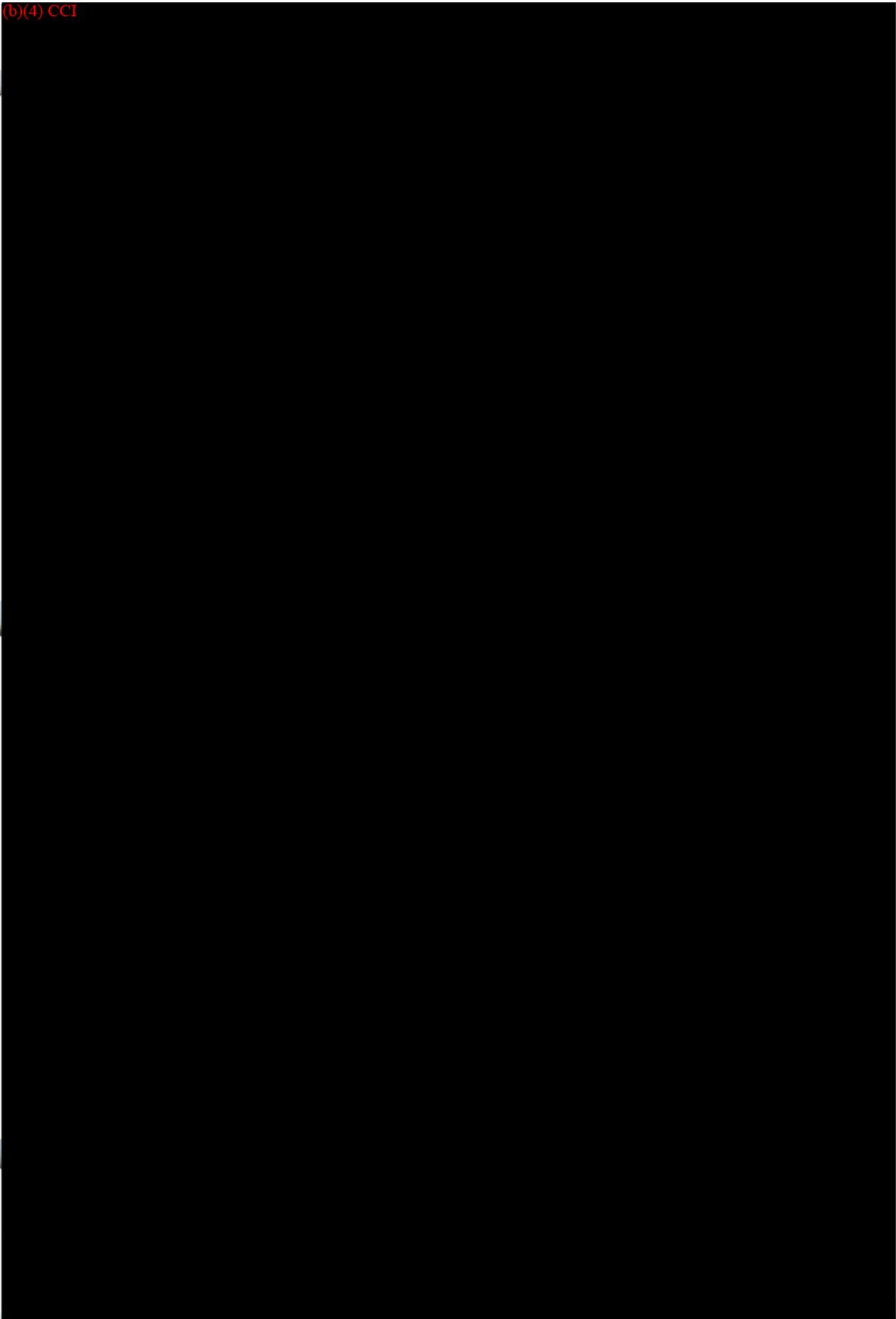
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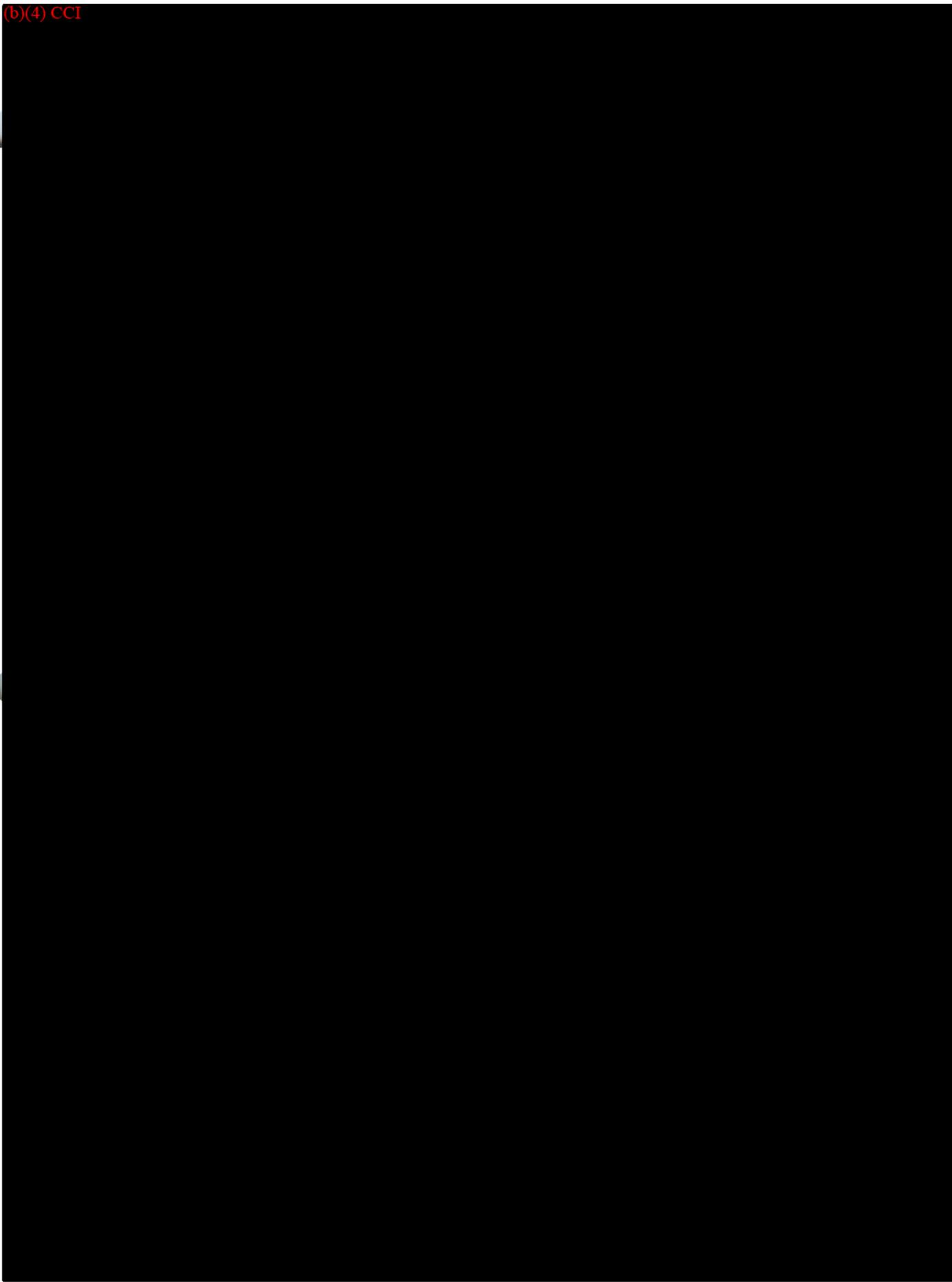
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