

JUN 2 2 2004

K040911

Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010**

**Non-Confidential Summary of Safety and Effectiveness
Page 1 of 3**

Dynatherm Medical, Inc.	Phone: (650) 777-4361
	Fax: (650) 777-4370
Official Contact:	Nathan Hamilton
Proprietary or Trade Name:	VitalHeat™
Common/Usual Name:	VitalHeat™
Classification Name:	Thermal Regulating System
Predicate Device:	Aquarius Medical Corporation Thermo-STAT – K970367 Aquarius Medical Corporation AcroTherm – K003368

Device Description:

The Dynatherm Medical, Inc. VitalHeat™

- Warming Mitt
- Control Unit

The VitalHeat™ is a compact, thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand). The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand), which should not impede standard patient care and/o full body access.

Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

Indicated Used:

The VitalHeat™ designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to hand.

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
Non-Confidential Summary of Safety and Effectiveness
Page 2 of 3**

Patient Population:

The system is for use with patients experiencing cold who are 18 years of age and older.

Environments of Use:

The device is intended for use throughout healthcare facilities.

Contraindications:

The VitalHeat™ is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

Page 3 of 3
510 (k) COMPARATIVE TABLE

COMPANY	DYNATHERM	AMC	AMC
PRODUCTS	VitalHeat™	ACROTHERM K003368	THERMO-STAT K970367
Intended use	Patient Temperature Control and Maintain	Patient Temperature Control and Maintain	Patient Temperature Control
Intended Environment of use	Healthcare Facilities	Healthcare Facilities	PACU
Contraindications	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease
Type	Sub Atmospheric Pressure/Water Paddle Disposable Mitt	Sub Atmospheric Pressure/Water Perfusion Pad in Camber	Negative Pressure/ Thermal Pad in Chamber
Pressure Device	Yes – Neg.	Yes – Neg.	Yes – Neg.
Sub-Atmospheric Pressure (mmHg)	40 ± 5 mmHg	40 ± 5 mmHg	40 – 60 mmHg
Electrical (AC)	Yes	Yes	No
Temperature Range	≤ 45 ° C	≤ 45 ° C	≤ 45 ° C
Application Site	Hand	Distal Limb	Distal Limb
Control System			
Control Type	Micro - Logic	Micro - Logic	N/A
Size - Controller	16 x 6 x 6 in.	14 x 6 x 5 in.	N/A
Weight	15.0 Lbs.	9.30 Lbs.	N/A
Mobility	Hand-Held IV Pole MTG Table Top	Hand-Held IV Pole MTG Table Top	N/A
Water Tank	200 ml	400 – 500 ml	N/A
Flow Rate	> 1000 ml/Min.	< 500 ml/Min.	N/A
Safety			
High Temperature Alarm	Yes	Yes	No
Water Level	Yes – Water Flow	Yes	N/A
Sub-Atmospheric Pressure	Yes LED and Audible	Yes LED and Audible	Yes LED Only
Timer	Yes	No	No
Seal	Yes	Yes	N/A



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2004

Dynatherm Medical, Inc.
c/o Mr. Nathan Hamilton
819 Mitten Road, Suite 42
Burlingame, CA 94010

Re: K040911
VitalHeat™
Regulation Number: 21 CFR 870.5906
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: June 3, 2004
Received: June 7, 2004

Dear Mr. Hamilton:

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.

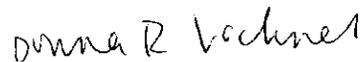
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Page 2 – Mr. Nathan Hamilton

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 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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040911

Device Name: VitalHeat™

Indications For Use:

The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by warming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Prescription Use X
(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)

Dana R. Volmer
(Division Sign-Off)
Division of Cardiovascular Devices

Page 1 of 1

510(k) Number: K040911



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2004

Dynatherm Medical, Inc.
c/o Mr. Nathan Hamilton
819 Mitten Road, Suite 42
Burlingame, CA 94010

Re: K040911
VitalHeat™
Regulation Number: 21 CFR 870.5906
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
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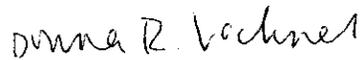
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Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

Indications for Use

510(k) Number (if known): K040911

Device Name: VitalHeat™

Indications For Use:

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Prescription Use X
(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)

Danna R. Vochner
(Division Sign-Off)
Division of Cardiovascular Devices

Page 1 of 1

510(k) Number K040911

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

May 21, 2004

DYNATHERM MEDICAL, INC.
c/o UNDERWRITERS LABORATORIES, INC. 510(k) Number: K040911
1655 SCOTT BLVD. Product: VITALHEAT
SANTA CLARA, CA 95050
ATTN: DENISE LEUNG KLINKER

Extended Until: 23-JUN-2004

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

1655 Scott Boulevard
Santa Clara, CA 95050-4169
United States Country Code (1)
(408) 985-2400
FAX No. (408) 296-3256
http://www.ul.com



K040911

May 19, 2004

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

Attention: Mr. Keith Foy
Reference: Dynatherm Medical, Inc., VitalHeat 510(k) Submission for Third Party Review, K040911
Subject: Request for extension of time.

Dear Mr. Keith Foy:

Dynatherm is requesting for a 30-days extension of time to complete the requested changes to their submission.

The response from Dynatherm dated May 19, 2004 is attached.

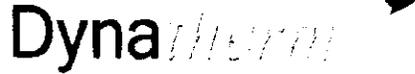
Best Regards,

Morten Simon Christensen
Staff Engineer & FDA 510(k) Office Coordinator
Medical Device Services
Phone (408) 876-2016
Fax (408) 556-6218

Vertical stamp: MAY 21 10:38 AM '04

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Handwritten initials: SJC 11

The logo for Dynatherm Medical, Inc. features the word "Dynatherm" in a stylized, italicized font. The "therm" part is in a lighter, more transparent font. To the right of the text is a graphic element consisting of a thick, black, curved line that tapers to a point, resembling a stylized flame or a dynamic arrow.

May 19, 2004

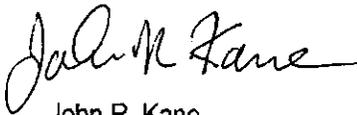
Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Underwriters Laboratories, Inc.
1655 Scott Blvd.
Santa Clara, CA 95050-4169
Phone: (408) 876-2016
Fax: (408) 556-6218

RE: K040911-510 (k) Premarket Notification VitalHeat™
Dated: April 23 2004
Received: April 26, 2004

Dear Morten:

We have reviewed the nine (9) questions raised, as you requested and believe that at this time Dynatherm Medical, Inc. would like to request a 30-day extension from FDA. Please contact me if you have any questions.

Best Regards,

A handwritten signature in black ink that reads "John R. Kane". The signature is written in a cursive, flowing style.

John R. Kane

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

April 23, 2004

DYNATHERM MEDICAL, INC.
c/o UNDERWRITERS LABORATORIES, INC. 510(k) Number: K040911
1655 SCOTT BLVD. Product: VITALHEAT
SANTA CLARA, CA 95050
ATTN: DENISE LEUNG KLINKER

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 requested information, 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. 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.

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If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

April 08, 2004

DYNATHERM MEDICAL, INC.

c/o UNDERWRITERS LABORATORIES, INC. 510(k) Number: K040911

1655 SCOTT BLVD.

Received: 08-APR-2004

SANTA CLARA, CA 95050

Product: VITALHEAT

ATTN: DENISE LEUNG KLINKER

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at <http://www.fda.gov/oc/mdufma>).

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 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.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

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

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K040911

FDA/CDRH
2004 APR -8 AM 10:39

April 6, 2004

CDRH / Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: Third Party 510(K) Submission for Dynatherm Medical Inc., VitalHeat™

Dear Madam/Sir:

Pursuant to FDA Accredited Persons Program for Third Party Reviews under the FDA Modernization Act of 1997 and as an authorized entity by and on behalf of Dynatherm Medical, we are submitting our review and recommendation on substantial equivalence of the enclosed 510(k) premarket notification by this manufacturer, prior to their introduction of the product into interstate commerce.

- 1. Name and address of third party: Underwriters Laboratories Inc.
1655 Scott Boulevard
Santa Clara, CA 95050-4169
- 2. Name and address of manufacturer: Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
- Establishment Registration No.: Sponsor has not received Registration No.
- 3. Name of the devices: VitalHeat™
- 4. Classification Panel: Cardiovascular Panel
- Classification Regulation Number: 870.5900
- Product Code: DWJ
- 5. Predicate Device & K Number: Aquarius Medical Corporation, Inc.
Thermo-STAT, K970367
- Aquarius Medical Corporation, Inc.
Acro Therm, K003368
- 6. Date first received by third party: February 12, 2004
- 7. Recommendation with respect to SE April 6, 2004

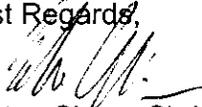
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FD 1099
April 6, 2004
Page 2/2

Enclosed herein is our complete review. The following attachments are provided.

Attachment No.	Name of Attachment
1	Third Party 510(k) Review Memo
2	Third Party 510(k) Pre-Market Notification
3	Third Party Review Checklist
4	Third Party SE Document Decision Making
5	Records of Deficiencies
6	Indication for Use Form
7	510(k) Summary of Safety and Effectiveness
8	Truthful and Accuracy Statement
9	Client Declaration and Authorization
10	Device Review Plan and Checklist
11	Activity Log
12	Conflict of Interest Form; UL & Sponsor Contract Forms
13	Predicate Device Information
14	Correspondences between Sponsor and UL
15	Sponsor's original 510(k) Submission

We certify that we continue to meet personnel qualification and have no financial interest in or conflict of interest with the above named manufacturer; statements made in the third party review are true and accurate to the best of our knowledge; our review is based on the 510(k) that we are submitting with the review; and we understand the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Best Regards,

Morten Simon Christensen
Reviewer
Medical Device Services
Tel: (408) 876-2016
Fax: (408) 556-6218

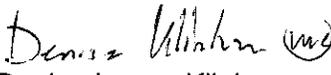
Reviewed by:

Denise Leung Klinker
Principal Reviewer
Medical Device Services
Tel: (408) 876-2566
Fax: (408) 556-6217

Table of Contents

1	Third Party 510(k) Review Memo
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3	Third Party Review Checklist
4	Third Party SE Document Decision Making
5	Records of Deficiencies
6	Indication for Use Form
7	510(k) Summary
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15	Sponsor's Original 510(k) Submission

April 6, 2004

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

Subject: Third Party 510(K) Review Memo for VitalHeat™

I. BACKGROUND

Name of Sponsor: Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
USA

Name of device: VitalHeat™

Device Intended Use:

The VitalHeat™ is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to hand.

Type of Submission:

Traditional 510(K)

Reason for Application:

Modification to own device. This submission is a significant modification of a previously cleared device. Aquarius Medical Corporation received an SE letter under K003368 cleared December 1997 for a product called AcroTherm™.

Checklists/guidance documents used during the review:

1. Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Provided in UL's Attachment 3)
2. Third Party "Substantial Equivalence " (SE) Decision Making (Provided in UL's Attachment 4)
3. Review Plan for the VitalHeat™ Thermal Regulating System. The Review Plan was reviewed by FDA on March 16, 2004 (Provided in UL's Attachment 10)
4. Checklist based on Review Plan (Provided in UL's Attachment 10)

II. CONTENT AND ORGANIZATION OF INFORMATION

Cover Letter:

In Dynatherm's February 12, 2004 cover letter and Section 1 of the original submission, the following information is provided.

1. Device's trade or proprietary name	VitalHeat™
2. Device's common or usual name	VitalHeat™
3. Device's classification name	Thermal Regulating System
4. The establishment registration number	The establishment registration number for Dynatherm Medical, Inc. is under application.
5. Regulation Number	21CFR 870.5900
Device Class	II
Classification Panel	Cardiovascular
Product Code	DWJ
6. Purpose of the submission	This submission is a significant modification of a previously cleared device. Aquarius Medical Corporation received an SE letter under K003368 cleared December 1997 for a product called AcroTherm™.
5. Predicate Devices and K Numbers	Aquarius Medical Corporation, Inc. Thermo-STAT, K970367 Cleared December 17, 1997 Aquarius Medical Corporation, Inc. AcroTherm, K003368 Cleared January 19, 2001

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Intended Use:

1. The Intended Use Statement as noted in Item I above is contained in Section 2.1, page 2 of 3 in the sponsor's original submission.
2. My analysis and opinion of the adequacy of the Intended Use information is that it satisfies the regulator requirement set forth in the 510(K).

Comparison of the Intended Use Statements

New Device	Predicate Devices		Comments
	Thermo-STAT K970367	AcroTherm K003368	
The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to hand.	The Thermo-STAT is designed to Non-Invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.	The AcroTherm is designed to Non-Invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.	There are no new claims made. Therefore, no new safety and effectiveness issues are raised.

3. My recommendation for the Intended Use is that it is considered substantially equivalent to the legally marketed predicate devices.
4. The Indications for Use Form for the new device is contained in Section 2.3 in the sponsor's original submission.

“The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.”

The Indication for Use for the two predicate devices is identical to the Indication for Use for the new device, and is contained in Section 15 and 16 in the sponsor's original submission.

5. My recommendation for the Indications for Use is that it is considered substantially equivalent to the legally marketed predicate devices.

Device Description/Principals of Operation:

1. Device Description is provided in Section 2.1 and 4 in the sponsor's original submission.

The Vital Heat™ temperature management device is a modification of the AcroTherm-K003368. The Vital Heat™'s technology of applying a sub-atmospheric pressure on a appendage and applying heat is the same as the Acrotherm

The VitalHeat™ is a compact, thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand). The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand), which should not impede standard patient care and/o full body access.

Current methods used in healthcare facilities, such as forced-air rewarming, can be ineffective in overcoming the “vasoconstrictive blockade.” The VitalHeat™ efficiently warms the body non-invasively from the inside out, including the vital organs that comprise the majority of the thermal core.

Hypothermia is defined as the condition of a temperature-regulating organism when core temperature is below the set range specified for the normal active state of the species. Hypothermia has significant clinical consequences, including:

1. Increased risk of cardiac mortality and morbidity.
2. Increased infection rates.
3. Increased recovery time.
4. Increased fluid requirements.

Recovery from cold and decreased core temperature are dependent on an individual’s ability to prevent further heat loss from the body core, while generating and/or maintaining as much heat/energy within the body core thermal compartment. When the core temperature falls below the desired set point, involuntary physiological responses occur to prevent further heat loss. Heat flux between the periphery (i.e., skin) and body core is a function of the amount of blood flowing between the core thermal compartment and the periphery (skin), especially the specialized heat transfer areas (palms of the hand, soles of the feet, cheeks, nose, and ears). The flow of blood to the skin is a function of peripheral vasomotor tone. When vasodilated, there is a free exchange of heat between the body core and the periphery. When vasoconstricted, this exchange of heat from the periphery to the body core is restricted.

A reduction in core temperature causes a vasoconstrictive response that is maintained until core temperature returns to the desired normothermic set point of the individual. This response is controlled, at a 4:1 ratio, by the body core temperature, versus the superficial (skin) temperature. Therefore, heating of the skin has only a limited effect on core temperature due to vasoconstrictive blockade resulting from the reduction in core temperature.

The VitalHeat™ approaches the rewarming dilemma by adding sub-atmospheric pressure combined with a thermal load applied to a specialized heat transfer area (hand). By mechanically distending the specialized heat exchange vessels, heat is transferred more efficiently to the body core.

The VitalHeat™ system comprises the following components:

1. Control unit with pre-connected Paddle
2. Disposable Warming Mitt.

Diagrams depicting the two main components and their subassemblies are in Attachment A.

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Sub Atmospheric Pressure Source:

A key ingredient of the technology is the ability to provide sub-atmospheric pressure in the localized area being treated. In a patient experiencing a reduction in core temperature, the VitalHeat™ acts to increase core body temperature and reduce the physical discomfort by the simultaneous application of heat and sub-atmospheric pressure to the treated area (hand). These areas are documented as primary heat exchangers that the body utilizes to respond to changes in core temperature. In a hypothermic patient, the application of heat alone to these same areas will not efficiently increase core body temperature due to the vasoconstrictive blockade of the blood vessels in the periphery.

The VitalHeat™ is designed to apply of 40 +/-5-mmHg sub-atmospheric pressure to the treated area. Treatment of a single appendage is sufficient to increase the heat transferred to the body core. This low level of sub-atmospheric pressure manually creates vasodilation in the treated appendage, thus allowing the thermal load applied to the skin to be more efficiently transferred to the blood stream and, ultimately, the body core.

The source of the sub-atmospheric pressure is a vacuum pump incorporated in the control unit.

Temperature Measurement:

In clinical tests performed with the Acrotherm cleared under K003368 thermocouple inserted into the ear was used to measure tympanic temperature. Tympanic temperature is considered to be an accepted measure of core body temperature. It is anticipated that routine methods (e.g., infrared thermometers used in the ear) will be the method used by most clinicians in assessing core body temperature. Because of the general availability of such devices, it is not anticipated that a body temperature-measuring device will be included with the VitalHeat™ system.

Controls to prevent overheating of the patient:

As the VitalHeat™ system rewarms cold patients, the thermoregulatory system of the body self-regulates to adapt vasomotor tone to changes in core temperature. As core temperature increases, the periphery circulatory system specializing in heat transfer increases the vasodilation, allowing for the effective elimination of excess heat. In the event the body is maximally vasodilated and heat is still applied, the patient will perspire to assist in the elimination of excess heat. Once core body temperature has been returned to an individual's set point, the body's own physiologic thermoregulatory system adapts to maintain that set point.

A series of single logic controls work together to ensure that the system operates safely.

Summary of Device Features

PRODUCT		VitalHeat™
Intended Use	Patient Temp. Management	
Type	Negative Pressure/ Water Heated Aluminum Dome	
Pressure Device	Yes-sub-atmospheric	

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Sub-atmospheric pressure (mmHg)	40±5
Electric (AC)	Yes
Temp. Range	(b)(4) Confidential and Proprietary Information
Application Site	Distal Limb (hand)
Disposable Type	Single use Mitt
Control System	
Controller Type	Micro-logic/hardware
Size	14x6x5 in
Weight	15 lb
Mobility	Hand-held
Water Tank	(b)(4) Confidential and Proprietary
Safety	
High Temperature Alarm	Yes
Water Flow Alarm	Yes
Sub-Atmospheric Pressure Alarm	Yes
Electrical Safety	Yes UL 2601-1 and IEC 601-1-2

The system is for use with patients 18 years of age and older.

The VitalHeat™ is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

For use in health care facilities, including hospitals, ICUs, Ors, Ers, PACU, burn units and medical/surgical floors.

The heater and power supply are operated under 120V AC. The power supply provides 12V DC power to the pumps for vacuum and water.

The heat exchanger paddle does not require maintenance. Periodic inspection for the function of the latch should be made. Cleaning of the paddle and is performed when needed with a mild hypoallergenic soap and water. A mild, non-toxic disinfectant spray can also be used.

The control unit and tubing set should be periodically inspected for damage. See the User's Manual Instructions in section 10 in the sponsor's original submission.

Engineering drawings and illustrations are provided in section 12 in the sponsor's original submission.

2. My analysis and opinion of the adequacy of the device description is that it satisfies the regulatory requirements for a 510(k).
3. My recommendation for the device description is that it is considered substantially equivalent to the legally marketed predicate device.

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Standards:

1. The Submission includes declaration of intent to comply with FDA recognized consensus standards, see Section 4.11 in Sponsor's original submission.
2. Compliance is intended for UL2601-1 for Electrical Safety Testing, and IEC 60601-1-2 for Electromagnetic Compatibility testing.
3. My analysis and opinion of the adequacy of the information is that compliance with UL 2601-1 and IEC 60601-1-2 will satisfy the regulatory requirements for a 510(k) of this type of device for electrical safety and electromagnetic compatibility.
4. My recommendation for the electrical safety is that it be considered substantially equivalent through the application of the UL 2601-1 and IEC 60601-1-2 standards.

Design and Performance Criterion and Testing:

1. The product specification, test plan, and test report is provided in section 13 in the sponsor's original submission.
2. My analysis and opinion of the adequacy of the information is that it satisfies the regulatory requirements for a 510(k) of this type of device.
3. My recommendation for the provided documentation is that it be considered substantially equivalent through the application of the described established criterion and tests.

Sterilization:

The device is sold non-sterile. Cleaning methods are provided in the User's Manual, see Section 10, page 9 of 11 in sponsor's original submission.

Biocompatibility:

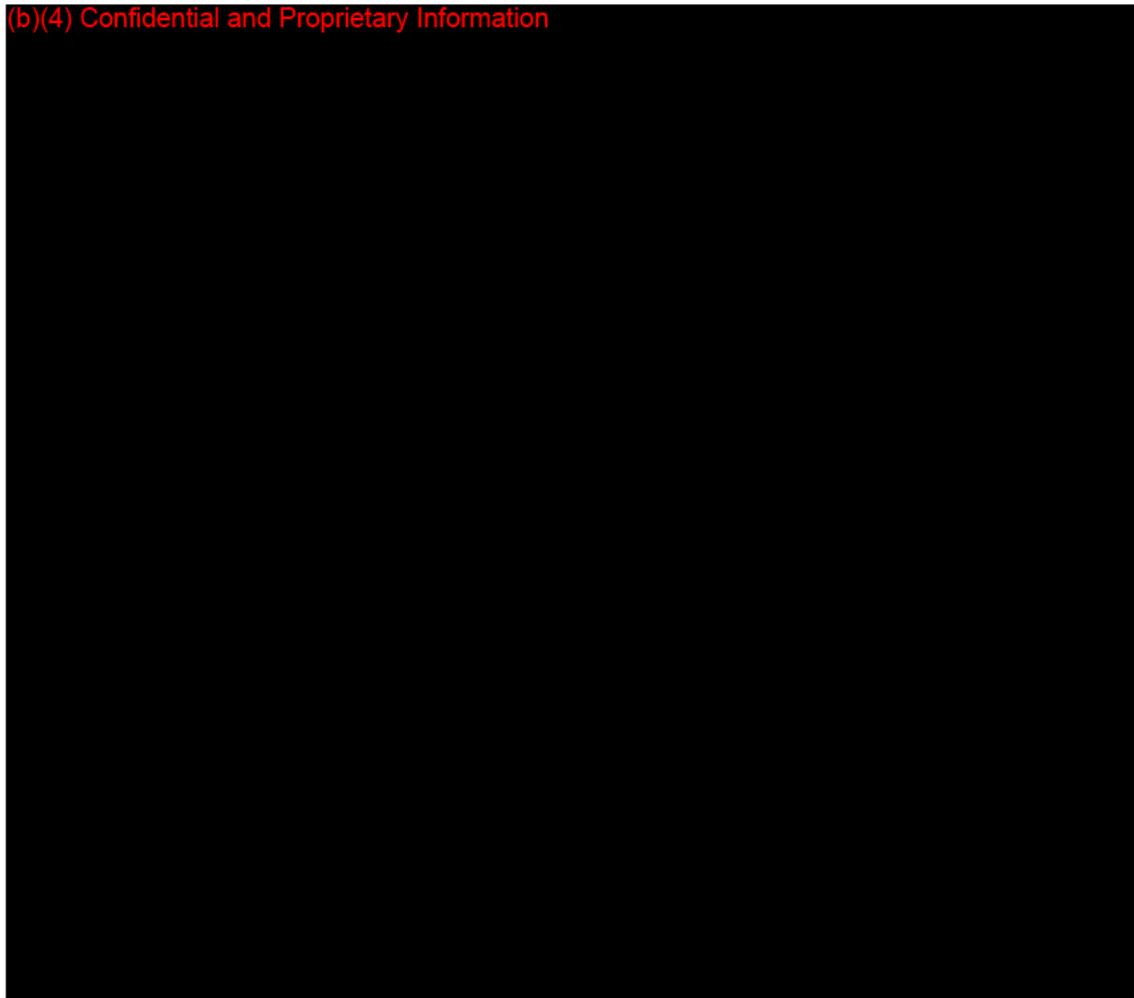
1. All materials utilized in the construction of the VitalHeat™ device are identified in section 6 in the sponsor's original submission.

Location	Component	Material	Patient Contact	Evaluation
----------	-----------	----------	-----------------	------------

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



* Same Material as Acrotherm Device - K003368

2. My analysis and opinion of the adequacy of the information is that it satisfies the requirement set forth for biocompatibility information.
3. My recommendation for the biocompatibility information is that it is considered substantially equivalent to the legally marketed predicate device.

Labels and Labeling:

1. The submission includes the proposed labels and labeling for the new device in Section 3, 10 and 11, in the sponsor's original submission. The indication for use, contraindications, warnings, and precautions are the same as the predicate device as described in Section 15 and 16 of this submission.
2. My recommendation for the labels and labeling is that it is considered substantially equivalent to the legally marketed predicate device.

Software:

The VitalHeat™ does not operate with software. Statement is provided in section 8 in the sponsor's original submission.

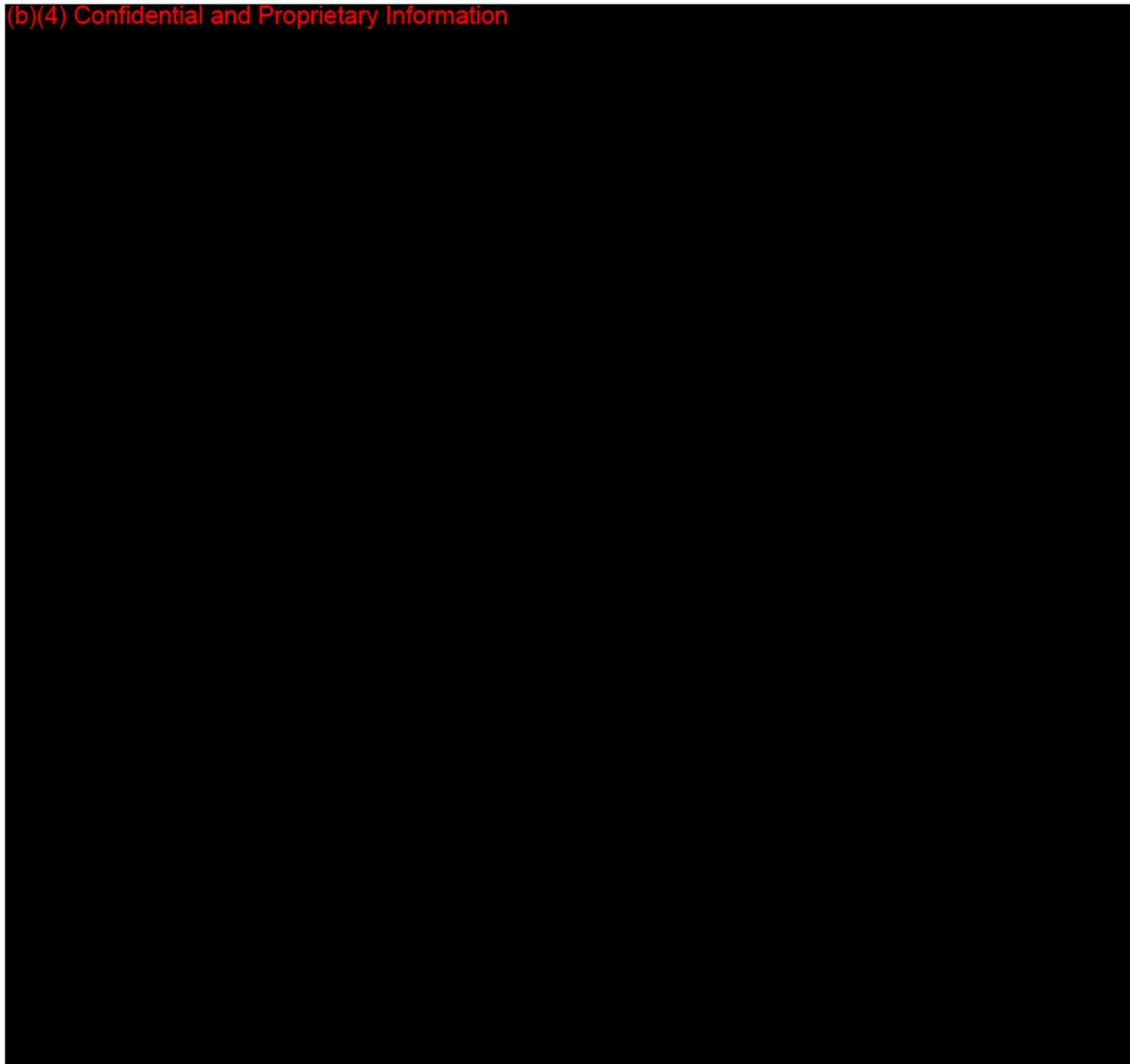
Descriptive Comparison to a Legally Marketed Device:

1. The predicate devices to which substantial equivalence is claimed are identified in section 2.1 in the sponsor's original submission.
2. Evidence that the legally marketed predicate devices were cleared for the same intended use is provided in section 14 and 15 in the sponsor's original submission.
3. A comparison between the new and the predicate devices is provided in Section 2.1 in the sponsor's original submission.

COMPANY	DYNATHERM	AMC	AMC
PRODUCTS	VitalHeat™	ACROTHERM K003368	THERMO-STAT K970367
Intended use	Patient Temperature Control and Maintain	Patient Temperature Control and Maintain	Patient Temperature Control
Intended Environment of use	Healthcare Facilities	Healthcare Facilities	PACU
Contraindications	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease
Type	Sub Atmospheric Pressure/Water Paddle Disposable Mitt	Sub Atmospheric Pressure/Water Perfusion Pad in Camber	Negative Pressure/ Thermal Pad in Chamber
Pressure Device	Yes – Neg.	Yes – Neg.	Yes – Neg.
Sub-Atmospheric Pressure (mmHg)	40 ± 5 mmHg	40 ± 5 mmHg	40 – 60 mmHg
Electrical (AC)	Yes	Yes	No
Temperature Range	≤ 45 ° C	≤ 45 ° C	≤ 45 ° C
Application Site	Hand	Distal Limb	Distal Limb
Control System			
Control Type	Micro - Logic	Micro - Logic	N/A
Size - Controller	16 x 6 x 6 In.	14 x 6 x 5 In.	N/A
Weight	15.0 Lbs.	9.30 Lbs.	N/A
Mobility	Hand-Held IV Pole MTG Table Top	Hand-Held IV Pole MTG Table Top	N/A
Water Tank	200 ml	400 – 500 ml	N/A
Flow Rate	> 1000 ml/Min.	< 500 ml/Min.	N/A

Safety			
High Temperature Alarm	Yes	Yes	No
Water Level	Yes – Water Flow	Yes	N/A
Sub-Atmospheric Pressure	Yes LED and Audible	Yes LED and Audible	Yes LED Only
Timer	Yes	No	No
Seal	Yes	Yes	N/A

(b)(4) Confidential and Proprietary Information



Water Tank 200ML vs. 400 – 500 ML

(b)(4) Confidential and Proprietary Information

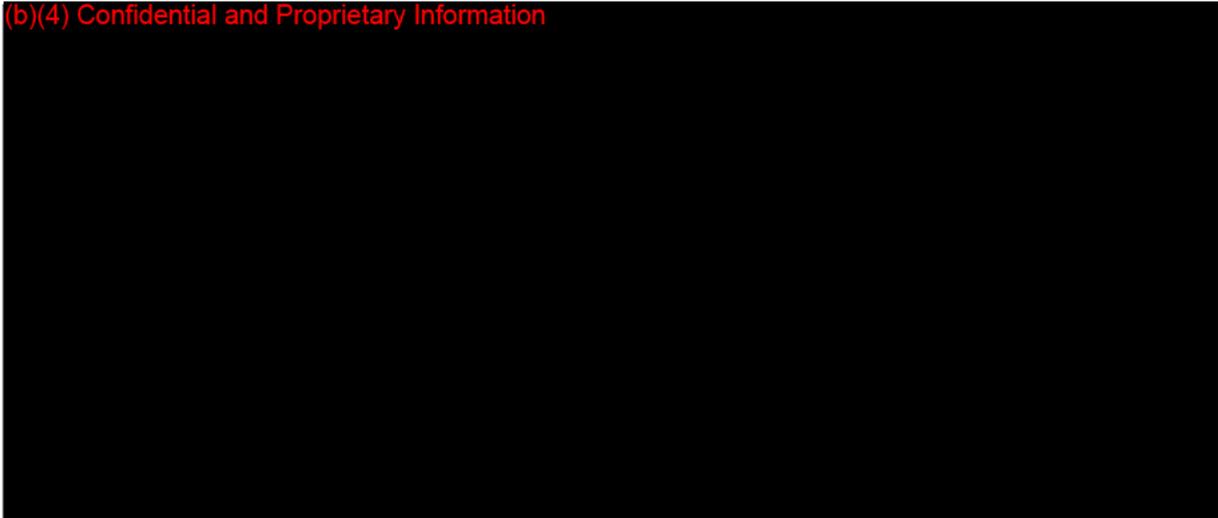


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Flow Rate > 1000 MI/Min. vs. < 500 MI/Min

The flow rate was increased to 1000 MI/Min. to enhance thermal response of the temperature control loop.

(b)(4) Confidential and Proprietary Information



Substantial Equivalence

The VitalHeat™ is viewed as substantially equivalent to the predicate devices since it:

Has the same intended uses:

The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by warming their body core. This accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Has the same environments for use:

Hospital/Healthcare environments where patient temperature management is necessary.

Has design features present in both predicates:

Warming Mitt – AcroTherm™

Water perfusion pad – AcroTherm™

Separate control panel for control and monitoring of the system – AcroTherm™

Warming Mitt which applies heat and sub-atmospheric pressure simultaneously –

AcroTherm™

Uses heated water as a thermal medium for application of heat through the thermal pad

– AcroTherm™

Is made of similar materials:

All patient contacting materials are biocompatible and have passed USP Class VI testing.

5. My analysis and opinion of the adequacy of the descriptive comparison is that it satisfies the regulator requirements for a 510(K).
6. My recommendation for the descriptive comparison between the new and the legally marketed devices is that it is considered Substantially Equivalent.

SMDA 1990 Information:

1. Summary of safety and effectiveness is provided in the section 2.1 in the sponsor's original submission.
2. Premarket Notification Truthful and Accurate Statement is provided in Section 2.2 in the sponsor's original submission.

Administration Items:

An Activity Log documenting telephone calls and correspondences between the Third Party Reviewer and other parties is enclosed in UL's Attachment 11 of this 510(K) submission.

III. RECOMMENDATION

Overall Recommendation:

We were satisfied with the comparison between the proposed device and the predicate devices as well as all the responses Dynatherm has provided in their submission package to address each of the items noted in the Review Plan for Thermal Regulating Devices, 21 CFR 870.5900.

All the data and information provided in Dynatherm's 510(K) submission is sufficient to support our recommendation for Substantially Equivalence.

THIRD PARTY PREMARKET NOTIFICATION (510(k)) CHECKLIST
FOR ACCEPTANCE DECISION

Part I - Acceptance/Non-Acceptance

Third Party:

Name Underwriters Laboratories, Inc.
Address 1655 Scott Boulevard
Santa Clara, CA 95050-4169
Contact Person Morten Simon Christensen
Telephone No. (408) 876-2016
Fax No. (408) 556-6218

For Foreign Third Parties, Specify A Domestic Correspondent:

Name _____
Address _____

Contact Person _____
Telephone No. _____
Fax No. _____

510(k) Owner (could be manufacturer, specifications developer, or other person preparing the 510(k):

Name Dynatherm Medical, Inc.
Address 819 Mitten Road, Suite 42
Burlingame, California 94010
Contact Person Mr. John Kane
Telephone No. (650) 777-4361
Fax No. (650) 777-4370

STOP!
Before completing Items 4 through 9 below, complete Part II checklist, Questions 1 through 27, beginning on Page 3 of this attachment.

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Part II - Checklist	YES	NO	Instructions
1. Is the device one that FDA has determined as being acceptable for third-party review?	✓		If NO, telephone DSMA for instructions ---STOP REVIEW
2. Is the device trade or proprietary name included?	✓		If NO, note deficiency in Attachment 4. <i>Yes, see Section 1 of sponsor's original submission.</i>
3. Is the device common or usual name included?	✓		If NO, note deficiency in Attachment 4. <i>Yes, see Section 1 of sponsor's original submission.</i>
4. Is the device classification name, class of the device, and regulation number (21 CFR 870.5900) included?	✓		If NO, note deficiency in Attachment 4. <i>Yes, see Section 1 of sponsor's original submission.</i>
5. Is the classification panel included?	✓		If NO, note deficiency in Attachment 4. <i>Yes, see Section 1 of sponsor's original submission.</i>
6. Has the applicant complied with Section 514 of the Act? (Section 514 relates to performance standards for Class II devices. At this time, there are no 514 standards. Therefore, your answer should be yes.)	✓		If NO, note deficiency in Attachment 4. <i>Yes.</i>
7. Does the submission include proposed labels, labeling, and advertisements (if available) that describe the device, its intended use, and directions for use (ODE Guidance Memorandum #G91-1)?	✓		If NO, note deficiency in Attachment 4. <i>Yes, see Section 3 for Labeling information, Section 10 for Operator's Manual, and Section 11 for Label information and instruction sheet, of sponsor's original submission.</i>
8. Does the submission contain the "Indications for Use" form (See Attachment 1b)?	✓		If YES, indicate page number: <i>Yes, see Section 2.3 of sponsor's original submission.</i> If NO, note deficiency in Attachment 4.

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Part II - Checklist	YES	NO	Instructions
9. Does the submission contain an acceptable <u>510(k) Summary of Safety and Effectiveness</u> or an acceptable <u>510(k) Statement</u> that safety and effectiveness information will be made available to any person upon request? For information on 510(k) Summaries and 510(k) Statements, see Attachment 1c.	✓		If YES, indicate page number: <i>Yes, see Section 2.1 of the sponsor's original submission.</i> If NO, note deficiency in Attachment 4.
10. Does the submission contain photographs of the device if applicable?	✓		If NO, note deficiency in Attachment 4. <i>Yes, see Section 10, page 6 of 11 of sponsor's original submission.</i>
11. Does the submission contain drawings for the device with dimensions and tolerances if applicable?	✓		If NO, note deficiency in Attachment 4. <i>Yes, see Section 12 of sponsor's original submission.</i>
12. Does the submission identify the device to which equivalence is claimed?	✓		If NO, note deficiency in Attachment 4. <i>Yes, see Section 1.11 of Sponsor's original submission. The predicate devices are:</i> <i>K970367: Aquarius Medical Corporation, Thermo-STAT.</i> <i>K003368: Aquarius Medical Corporation, Acro Therm.</i>

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Part II - Checklist	YES	NO	Instructions
<p>13. If the answer to Question 12 is YES, did the applicant identify:</p> <p>a. Predicate device (referred to as marketed device)?</p> <p>b. Legally marketed device (referred to as marketed device)?</p> <p>Note: A predicate device is a device that was legally in commercial distribution in the U.S. on or before May 28, 1976 (referred to as a preamendments device) or a device that was marketed after May 28, 1976 (referred to as a post amendments device) that was reclassified from Class III to Class I or II. A marketed device can be a predicate device but is most often a device that FDA has determined is SE to another marketed device (21 CFR 807.92(a)3). <u>IT IS YOUR RESPONSIBILITY TO MAKE SURE THAT THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE IDENTIFIED IS LEGITIMATE.</u> If it is not, the review must STOP. Telephone DSMA for assistance.</p>	✓		<p><i>Yes, see Section 1.11 of Sponsor's original submission. The predicate devices are:</i></p> <p><i>K970367: Aquarius Medical Corporation, Thermo-STAT.</i></p> <p><i>K003368: Aquarius Medical Corporation, Acro Therm.</i></p>
<p>14. Does the submission contain information about the marketed device(s) identified in Questions 12 and 13 above to which equivalence is claimed, including labeling and a description of the device?</p>	✓		<p>If NO, note deficiency in Attachment 4.</p> <p><i>Yes, see Section 15 and 16 of sponsor's original submission.</i></p>
<p>15. Does the submission contain a statement/comparison of similarities and/or differences between the new device and the marketed device? (The new device that is the subject of this 510(k) can be either a new device or a modification to the existing device.)</p>	✓		<p>If NO, note deficiency in Attachment 4.</p> <p><i>Yes, see Section 5, Comparison to Predicates, of sponsor's original submission.</i></p>
<p>16. Does the submission contain the Truthful and Accurate Statement (see Attachment 1d for information)?</p>	✓		<p>If YES, indicate page number:</p> <p><i>Yes, see Section 2.2 of sponsor's original submission.</i></p> <p>If NO, note deficiency in Attachment 4.</p>

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Part II - Checklist	YES	NO	Instructions
17. Does the submission contain the submitter's name, address, contact person, telephone number, and fax number?	✓		If NO or if unacceptable, note deficiency in Attachment 4. <i>Yes, See cover page of Sponsor's original submission.</i>
18. If there is a representative or consultant, does the submission contain their name, address, contact person, telephone number, and fax number?	✓		If NO, note deficiency in Attachment 4. <i>Not applicable since consultant was not used.</i>
19. Does the submission contain a table of contents with pagination?	✓		If NO, note deficiency in Attachment 4. <i>Yes, a table of contents follows immediately after the cover page.</i>
20. If the submitter has a manufacturing facility (contract or owned), and/or a sterilization facility (contract or owned), is the address(es) contained in the submission?	✓		If deficient, note in Attachment 4. <i>No contracted manufacturing facilities. Device is sold non-sterile. Sponsor's company address provided on cover page of sponsor's original submission.</i>
21. Does the submission contain a comparison table of the new device to the marketed device?	✓		If NO, note deficiency in Attachment 4. <i>Yes, see Section 5 of Sponsor's original submission.</i>
22. Does the submission contain information about the action taken to comply with voluntary standards?	✓		If NO, note deficiency in Attachment 4. <i>Yes, see Section 9 and 13 of Sponsor's original submission.</i>

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Part II - Checklist	YES	NO	Instructions
<p>23. Does the submission contain performance data (can be bench or animal but not clinical), i.e.:</p> <p>---- Is there performance data for the marketed device?</p> <p> a. Bench Testing? b. Animal Testing?</p> <p>___ Is there performance data for the new device?</p> <p> a. Bench Testing? b. Animal Testing?</p>	<p>✓</p>	<p>✓ ✓ ✓ ✓</p>	<p>If NO and data are necessary, note deficiency in Attachment 4.</p> <p><i>Not applicable since this is a modification to own predicate device.</i></p> <p><i>Yes, see Section 9 of Sponsor's original submission. Bench testing provided to show performance to established criteria.</i></p> <p><i>Animal testing not applicable.</i></p>
<p>24. If the device is labeled as sterile, does the submission contain sterilization data?</p>	<p>✓</p>		<p>If NO, note deficiency in Attachment 4.</p> <p><i>N/A. The device is not sterile.</i></p>
<p>25. Does the device incorporate a computer or computer software?</p> <p> a. If YES, is there information about the hardware? b. If YES, is there information about the software?</p>		<p>✓ ✓</p>	<p><i>N/A. The device does not incorporate a computer or computer software.</i></p>
<p>26. Is there a specific guidance document for this type of device?</p>		<p>✓</p>	<p>If YES, continue review with checklist from the specific guidance document as required.</p> <p><i>No, this is a pilot program device. A review plan has been developed by the Accredited Person reviewer and was reviewed by FDA on 3/16/04. See Section 10 of Third Party submission.</i></p> <p>If NO, answer question 27.</p>
<p>27. Is this 501(k) sufficiently complete to allow substantive review?</p>	<p>✓</p>		<p>If YES, continue review using specific guidance document or if no specific guidance document, continue the review using documentation forms.</p> <p><i>Review plan develop by Third Party and reviewed by FDA. See Section 10 of Third Party submission.</i></p> <p>If NO, note deficiency in Attachment 4.</p>

THIRD PARTY REVIEW CHECKLIST

1. Is this 510(k) eligible for third-party review, i.e.:	Yes	No
a. Is the device on the list of eligible devices?*	✓	
b. Can a determination of substantial equivalence be made without clinical data?	✓	
c. Are you aware of the 510(k) holder being the subject of an Integrity Investigation?		✓

IF THE ANSWER IS "NO" TO A or B above, or "YES" to C above, PLEASE BRING THE SUBMISSION TO PRINCIPAL REVIEWER IMMEDIATELY.

Are the following elements included in the submission:

2. A cover letter signed by the third party's official correspondent clearly identifying:	Yes	No
a. The purpose of the submission	✓	
b. The name and address of the third party	✓	
c. The name and address of the 510(k) holder	✓	
d. The name of the device (trade name, common or usual name, and FDA classification name)	✓	
e. The third party's recommendation with respect to the substantial equivalence of the device	✓	
f. The date the third party first received the 510(k) from the 510(k) holder	✓	

3. A letter signed by the 510(k) holder authorizing the third party to submit the 510(k) on its behalf and to discuss its contents with FDA.	✓	
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4. The complete 510(k) conforming to FDA's established requirements relating to content and form of such submissions.	✓	
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5. A complete review of the 510(k), signed by all personnel who conducted the third-party review and by an individual within the third party responsible for supervising third-party reviews, with a recommendation concerning the substantial equivalence of the device.	✓	
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Page 2 - Third Party Review Checklist

6. A certification that:	Yes	No
a. The third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA	✓	
b. Statements made in the third-party's review are true and accurate to the best knowledge of the third party	✓	
c. The third-party's review is based on the 510(k) that it is submitting with the review	✓	
d. The third party understands that the submission to the government of false information is prohibited	✓	

7. Are the following forms included in the submission as discussed in the Center's guidance document entitled Third Party Review-An Instruction Manual for Conducting Reviews of Premarket Notifications:	Yes	No
a. Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Parts I and II) (Attachment 2)	✓	
b. Record of Deficiencies, if applicable (Attachment 5)	✓	
c. Indications of Use Form (Attachment 6)	✓	
d. 510(k) Summary or Statement (Attachment 7)	✓	
e. 510(k) Truthful and Accurate Statement (Attachment 8)	✓	
f. Third Party "Substantial Equivalence" (SE) Decision Making Documentation (Attachment 9)	✓	

IF ANY OF THE ABOVE INFORMATION IS NOT INCLUDED WITH THE THIRD PARTY'S SUBMISSION OR IS NOT ADEQUATE, CONTACT THE THIRD PARTY AND ATTEMPT TO RESOLVE THE DEFICIENCY. PLEASE INCLUDE A MEMORANDUM TO THE RECORD OF THE TELEPHONE CALL. WHEN THE INFORMATION IS RECEIVED, PLEASE REVISE THIS CHECKLIST OR COMPLETE A NEW ONE.

COMMENTS: _____

*If the third party incorrectly classified the device and it is not a device type eligible for third-party review, please bring to Principal Reviewer.

NARRATIVE DEVICE DESCRIPTION

1. Intended Use:

The VitalHeat™ is designed to non-invasively treat hypothermic patients by warming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain a drug or biological product as a component? Is this device a kit? Provide a summary about the device's design, materials, physical properties, and toxicology profile if important.

Summary:

The VitalHeat™ temperature management device is a modification of the AcroTherm-K003368. The Vital Heat™'s technology for applying a sub-atmospheric pressure on a appendage and applying heat is the same as the AcroTherm.

The VitalHeat™ device is designed to provide the clinician a tool for manipulation of a patient's temperature. Patients undergoing anesthesia, in surgery, in the emergency room, or in intensive care can have substantial alterations to their thermal state. Hypothermia, the typical outcome, results from anesthetic induced impairments to thermoregulatory control. The VitalHeat™ device operates under the principle of treating cold described in "Recovery from mild hypothermia can be accelerated by mechanically distending blood vessels in the hand", Grahn et al., *J. Appl. Physiol.* 85(5): 1643-1648, 1998. The patient's hand is secured into a sealed mitt. A heat source provides heat transfer to blood passing through the hand. A vacuum system provides sub-atmospheric pressure within the mitt to mechanically vasodilate subcutaneous vascular structures. This vacuum in conjunction with topical application of heat which opens arteriovenous valves, significantly increases local blood flow. Increased local blood flow facilitates greater heat transfer to the body core, and ultimately increasing heat content to the whole body. The device operates in an ON/OFF mode. The device provides control panel indicators to show if the device is functioning properly and warning indicators to alert the clinician if the device has malfunctioned. The device is equipped with safety features, which under certain circumstances will cause the system to shut down.

The VitalHeat™ is not implanted, life supporting or life sustaining, sterile, a kit, single use, or for home use. The VitalHeat™ does not contain software, a drug or any biological products.

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Explanations to “YES” and “NO” Answers To Questions On Page 1 As Needed

1. Explain why not a device:
N/A
2. Explain why not subject to 510(k):
N/A
3. How does the new indication differ from the predicate device's indication:
N/A
4. Explain why there is or is not a new effect or safety or effectiveness issue:
N/A
5. Describe the new technological characteristics:
N/A
6. Explain how new characteristics could or could not affect safety or effectiveness:
N/A
7. Explain how descriptive characteristics are not precise enough:
N/A
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
N/A
9. Explain why existing scientific methods can not be used:
N/A
10. Explain what performance data is needed:
N/A
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
N/A

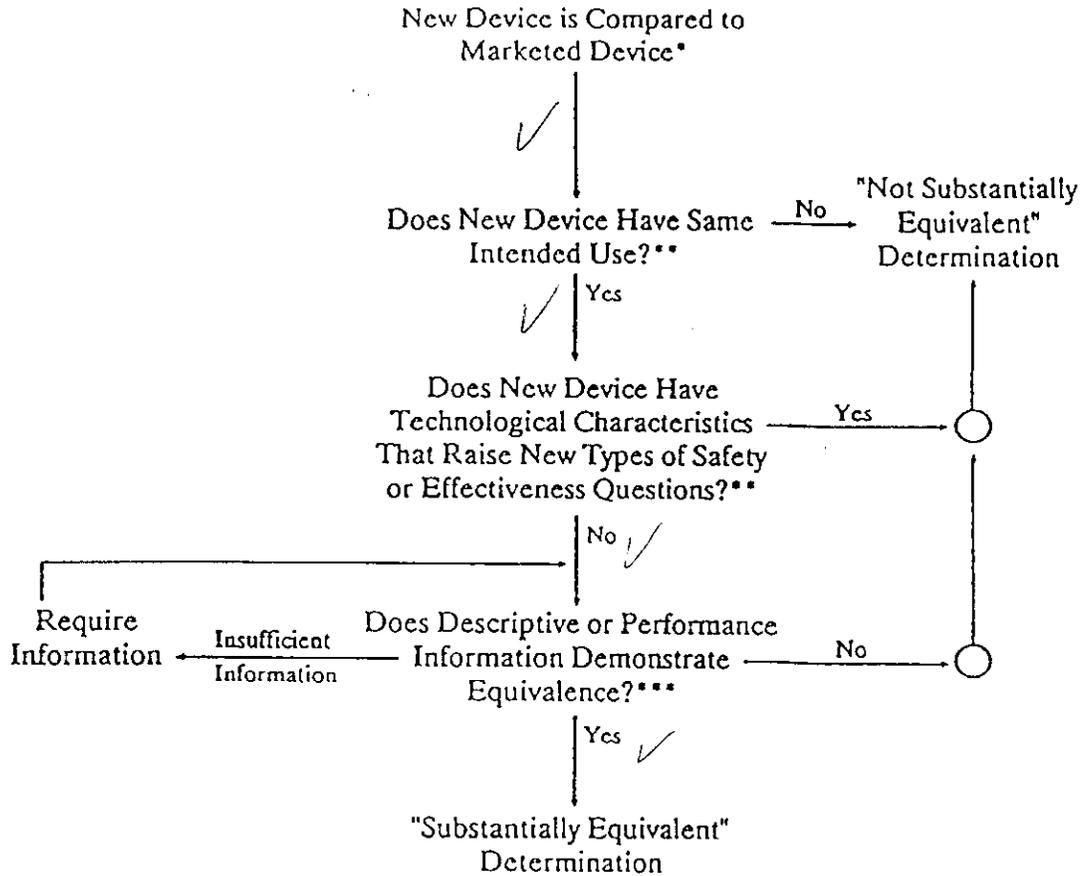
104

Record of Deficiencies

Describe in detail the additional information that is required:
N/A

(Attach additional pages as needed. Please number.)

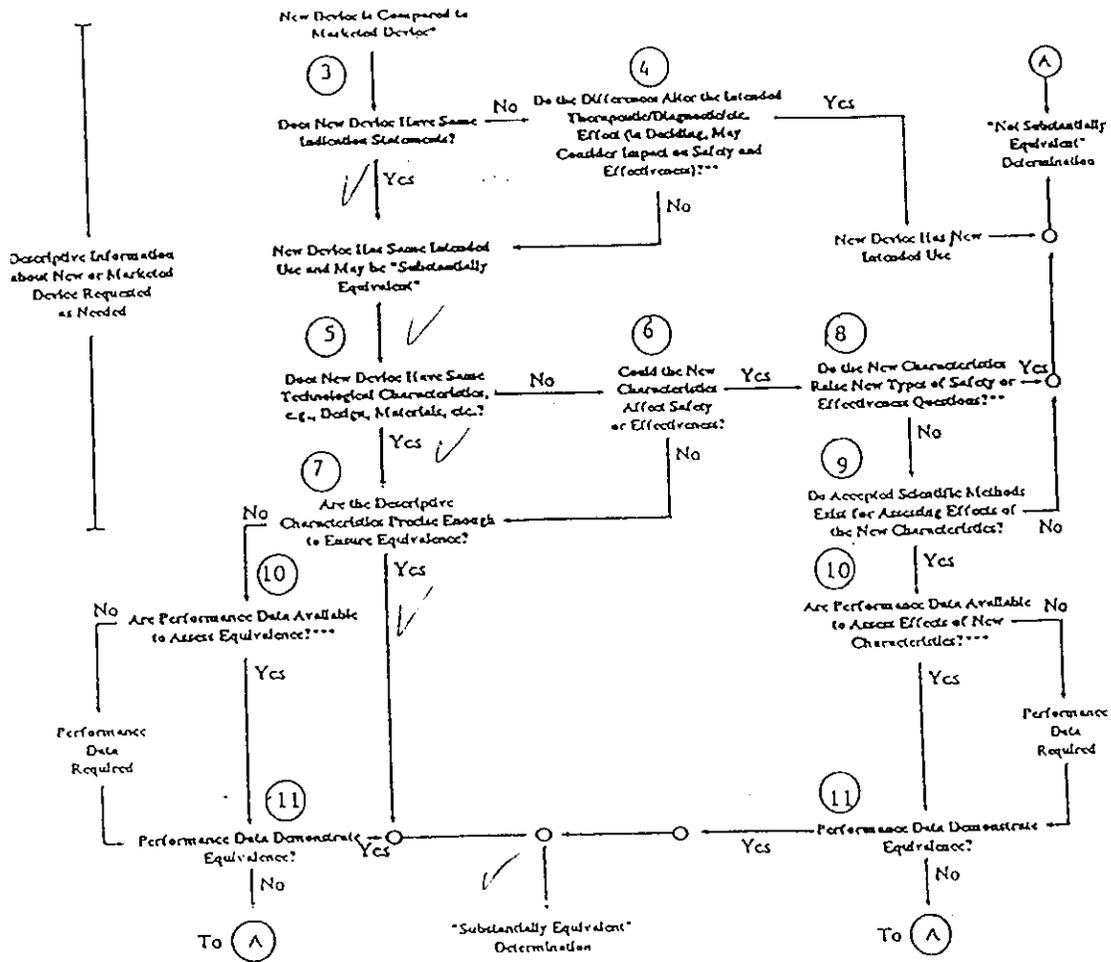
510(k) "SUBSTANTIAL EQUIVALENCE"
DECISION-MAKING PROCESS (OVERVIEW)



- * 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) device is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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510(K) "SUBSTANTIAL EQUIVALENCE"
DECISION-MAKING PROCESS (DETAILED)



- * 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) device is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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Indications for Use

510(k) Number (if known):

Device Name: VitalHeat™

Indications For Use:

The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by warming their body core. This accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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 _____

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Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
Non-Confidential Summary of Safety and Effectiveness
Page 1 of 3**

Dynatherm Medical, Inc.	Phone: (650) 777-4361
	Fax: (650) 777-4370
Official Contact:	Nathan Hamilton
Proprietary or Trade Name:	VitalHeat™
Common/Usual Name:	VitalHeat™
Classification Name:	Thermal Regulating System
Predicate Device:	Aquarius Medical Corporation Thermo-STAT – K970367 Aquarius Medical Corporation AcroTherm – K003368

Device Description:

The Dynatherm Medical, Inc. VitalHeat™

- Warming Mitt
- Control Unit

The VitalHeat™ is a compact, thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand). The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand), which should not impede standard patient care and/o full body access.

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**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.1 Summary of Safety and Effectiveness

Indicated Used:

The VitalHeat™ designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to hand.

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
Non-Confidential Summary of Safety and Effectiveness
Page 2 of 3**

Patient Population:

The system is for use with patients experiencing cold who are 18 years of age and older.

Environments of Use:

The device is intended for use throughout healthcare facilities.

Contraindications:

The VitalHeat™ is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

1/2

Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

Page 3 of 3

510 (k) COMPARATIVE TABLE

COMPANY	DYNATHERM	AMC	AMC
PRODUCTS	VitalHeat™	ACROTHERM K003368	THERMO-STAT K970367
Intended use	Patient Temperature Control and Maintain	Patient Temperature Control and Maintain	Patient Temperature Control
Intended Environment of use	Healthcare Facilities	Healthcare Facilities	PACU
Contraindications	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease
Type	Sub Atmospheric Pressure/Water Paddle Disposable Mitt	Sub Atmospheric Pressure/Water Perfusion Pad in Camber	Negative Pressure/ Thermal Pad in Chamber
Pressure Device	Yes – Neg.	Yes – Neg.	Yes – Neg.
Sub-Atmospheric Pressure (mmHg)	40 ± 5 mmHg	40 ± 5 mmHg	40 – 60 mmHg
Electrical (AC)	Yes	Yes	No
Temperature Range	≤ 45 ° C	≤ 45 ° C	≤ 45 ° C
Application Site	Hand	Distal Limb	Distal Limb
Control System			
Control Type	Micro - Logic	Micro - Logic	N/A
Size - Controller	16 x 6 x 6 In.	14 x 6 x 5 In.	N/A
Weight	15.0 Lbs.	9.30 Lbs.	N/A
Mobility	Hand-Held IV Pole MTG Table Top	Hand-Held IV Pole MTG Table Top	N/A
Water Tank	200 ml	400 – 500 ml	N/A
Flow Rate	> 1000 ml/Min.	< 500 ml/Min.	N/A
Safety			
High Temperature Alarm	Yes	Yes	No
Water Level	Yes – Water Flow	Yes	N/A
Sub-Atmospheric Pressure	Yes LED and Audible	Yes LED and Audible	Yes LED Only
Timer	Yes	No	No
Seal	Yes	Yes	N/A

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**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.2 Premarket Notification Truthful and Accurate statement

I certify that, in my capacity as a President of Dynatherm Medical, Inc, I believe to the best of my knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material fact has been omitted.



Nathan Hamilton
President/CEO
Dynatherm Medical, Inc.

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Client Declaration and Authorization

As an officer of Dynatherm Medical Inc. (Company), the undersigned hereby

1. Declare that the file and all relevant materials pertaining to the 510(k) in this review will be made available to FDA upon reasoned request.
2. Declare that there is no other application lodged with another third party organization, including other UL operations or FDA, for the work anticipated in the application.
3. Authorize UL to submit the 510(k) to FDA on behalf of the Company and to discuss its contents and all related materials with FDA.
4. Declare that we understand that UL is not required to provide notice to us when any material associated with UL's files is made available to FDA

Reference: Vitalheat™ (Subject 510(k) submission)

Company: Dynatherm Medical, Inc.


Signature

2-11-04
Date

H. LAWSON FISHER
Print Name

V.P. Engineering
Position

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Review Plan Checklist for Thermal Regulating System, 21 CFR 870.5900
(February 23, 2004)

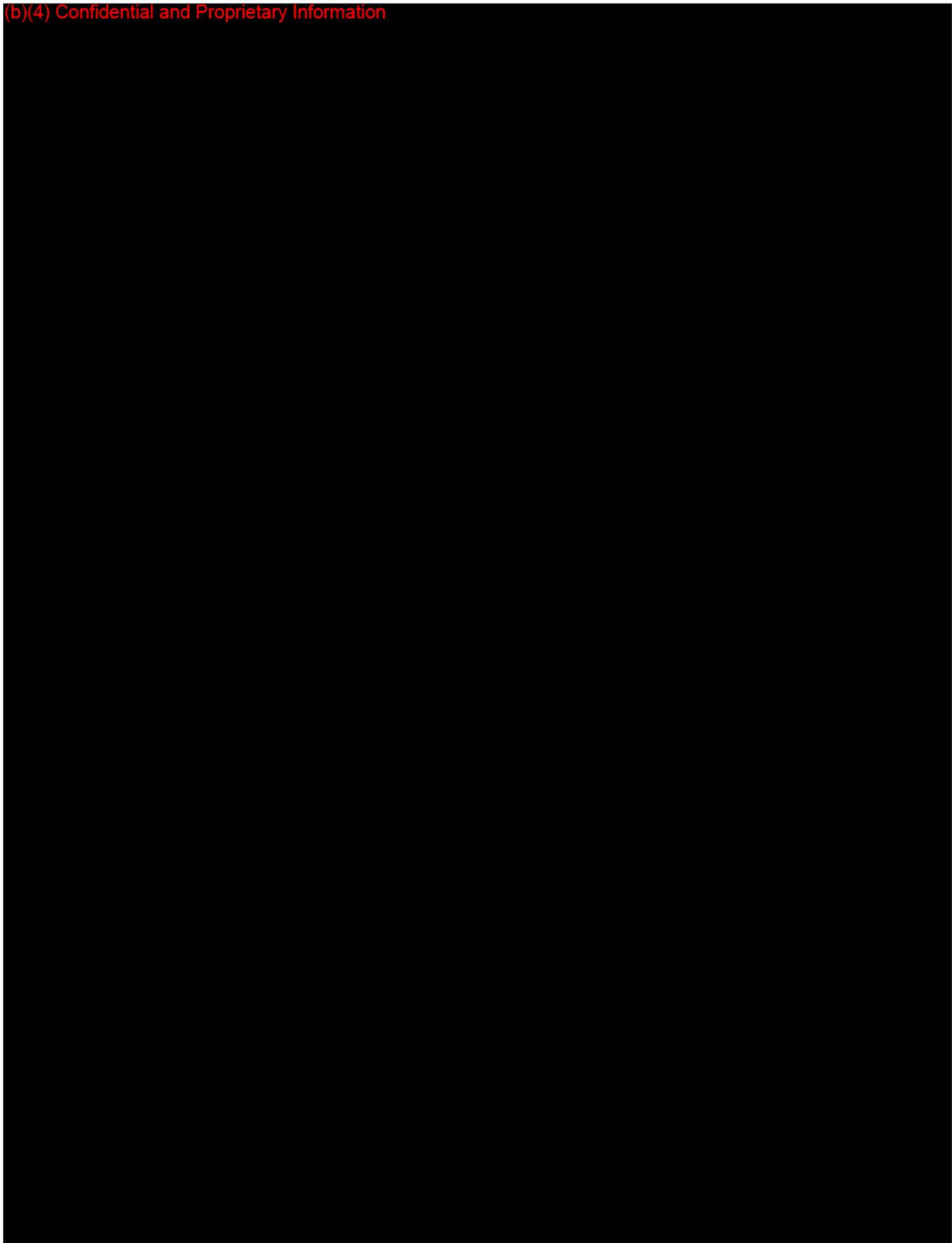
No.	Requirement	Comment/Location in Submission
	General Information	
A	Administrative Information	
1	Cover Letter	Cover Letter provided.
2	Table of Contents	Table of Contents provided.
3	Submitter's Information	Provided in Cover Letter.
4	Device Trade Name	Section 1.4. VitalHeat™
5	Device Common name	Section 1.4. VitalHeat™
6	Classification Information	Section 1.5, 1.6, 1.7, 1.9. Class II, Reg. No. 870.5900 DWJ, Thermal Regulation System.
7	Classification Panel	Section 1.8. Cardiovascular Panel.
8	Device to which Equivalence is claimed	Section 1.11. K970367, K003368.
9	Indications for Use	Section 2.3. Identical to predicate IFU.
	Device Descriptive Information	
B.1	Intended Use	Section 1.13, 2.1. Identical to predicate Intended Use.
C	Device Description	
1	Description of device	Section 4.0, 4.1, 10.0
2	Configurations and Functions	Section 4.0, 4.1, 10.0
3	Interconnection	Section 4
4	Photographs/Engineering Drawings	Section 10, 12
5	Temperature Range of Device	Section 2, 5
6	Temperature Range at Skin Surface	Section 2, 5
7	Flow rate, Pressure, Liquid Used	Section 2, 5
8	Anatomical Sites	Section 2, 5
9	Location Device is to be Used	Section 2, 5
10	Target Population	Section 2, 5
D	Performance	
1	Patient Safety Testing	Section 4.11
2	EMI Testing	Section 4.11

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E.1	Sterilization	Section 7. Not a sterile device. Section 10. Cleaning method.
F	Materials/Biocompatibility	
1	Materials Used	Section 6
2	Material Differences	Section 6
3	Materials in Contact with Patient	Section 6
4	Processing of Materials	Section 6
G	Labeling	
1	User's Manual/Packaging	Section 3, 4, 10, 11
2	Promotional Materials for New and Predicate Devices	Section 4, 15, 16
H.1	Software	Not applicable. Device not operating with software.
I	Substantial Equivalence Information	
1	Identify Predicate Device	Section 1.11
2	Evidence of Predicate Device	Section 15, 16
3	Written Description of Similarities /Differences	Section 5.1
4	Table of Similarities/Differences	Section 5
J	510(k) Summary or Statement	
1	Summary OR	Section 2.1
2	Statement	Not applicable.
K.1	Truth and Accuracy Statement	Section 2.2

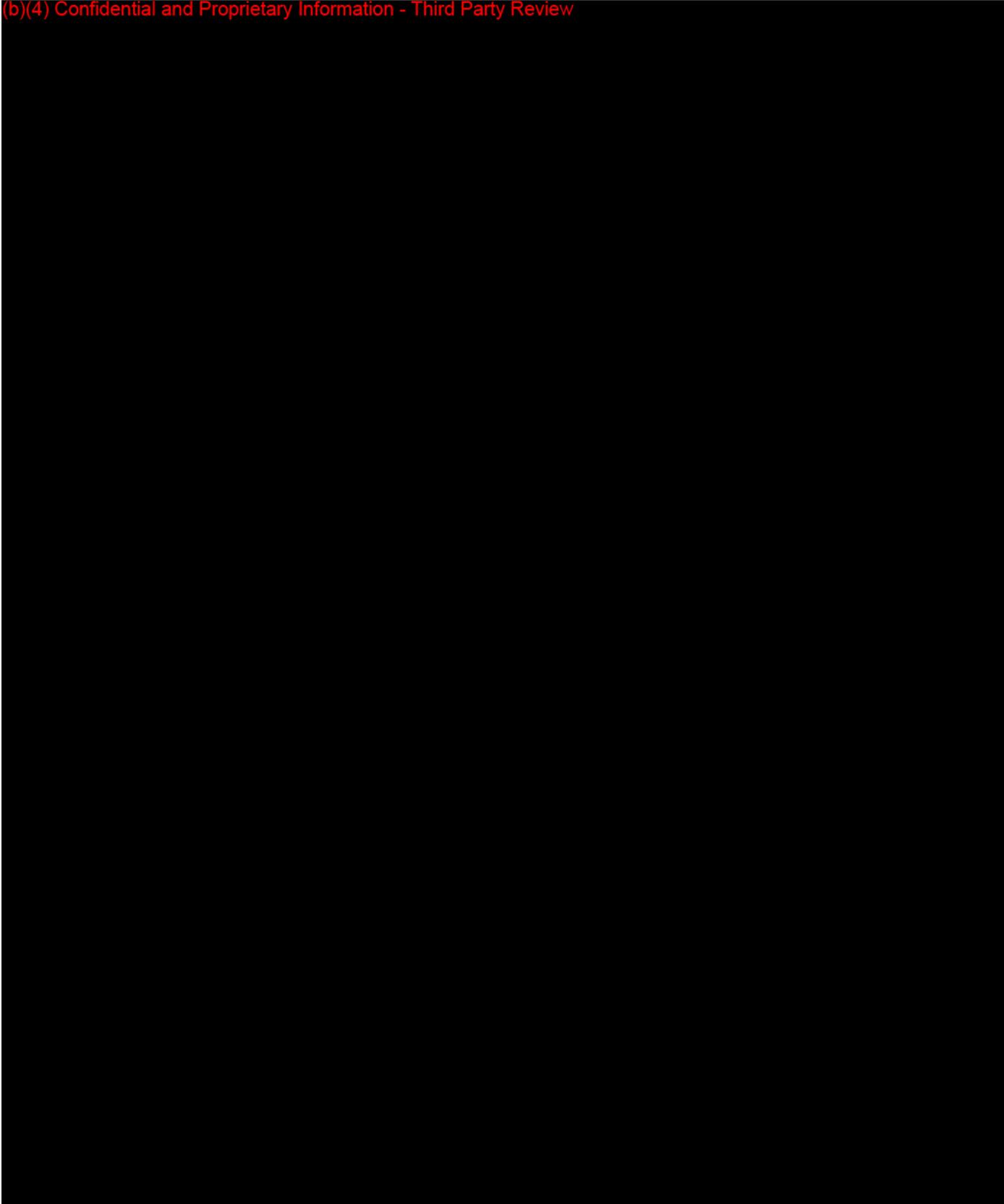
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(b)(4) Confidential and Proprietary Information



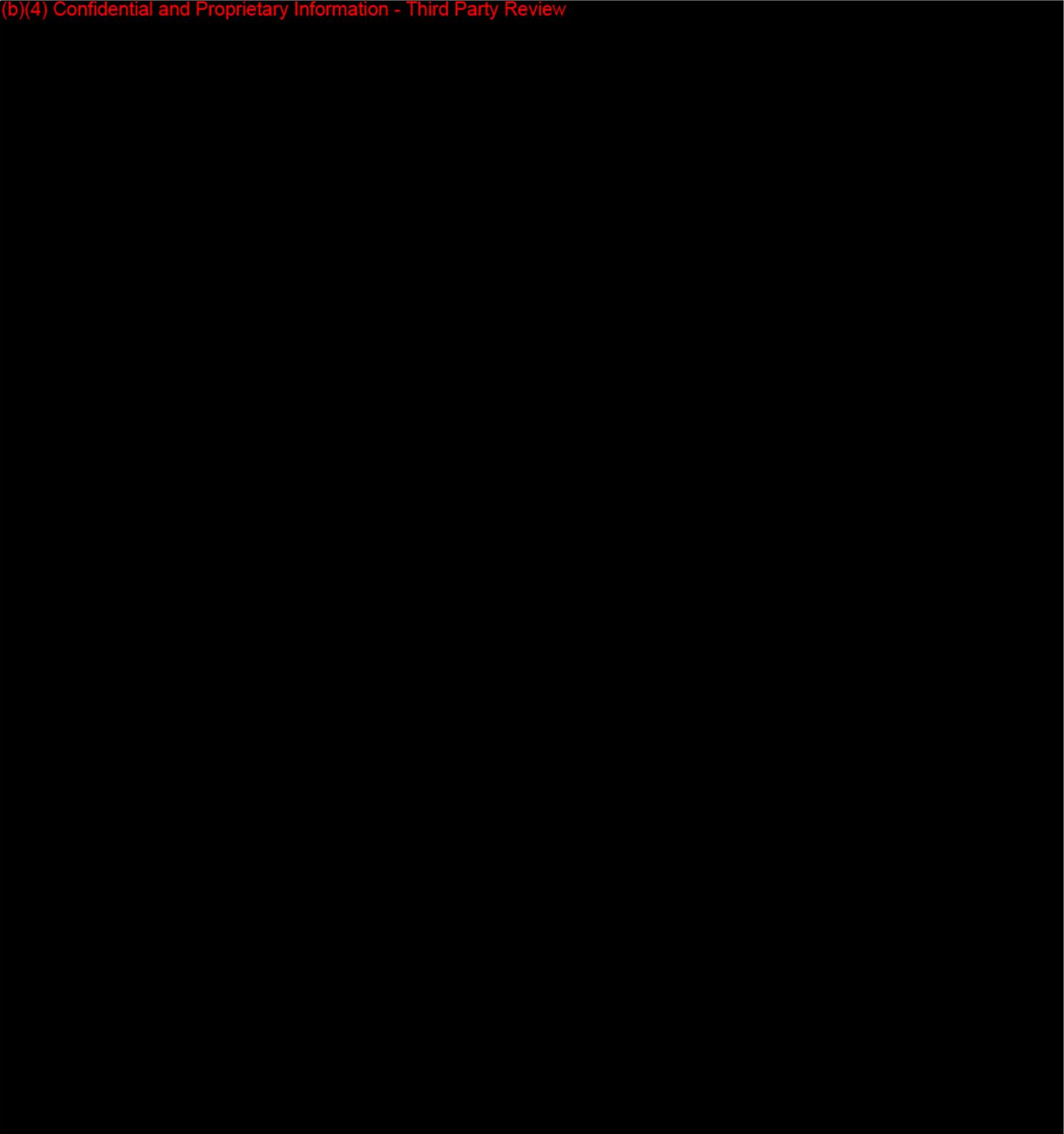
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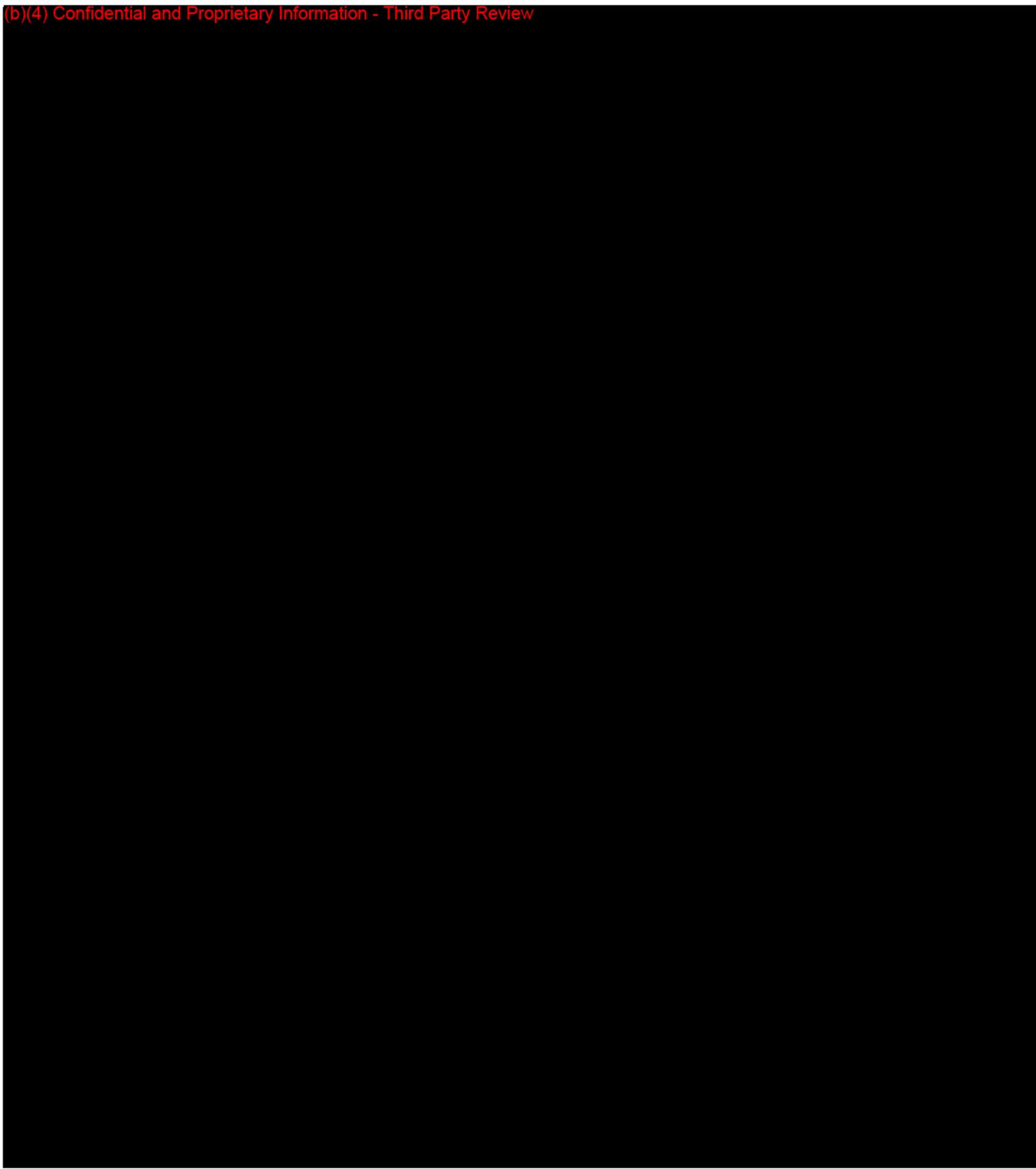


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(b)(4) Confidential and Proprietary Information - Third Party Review

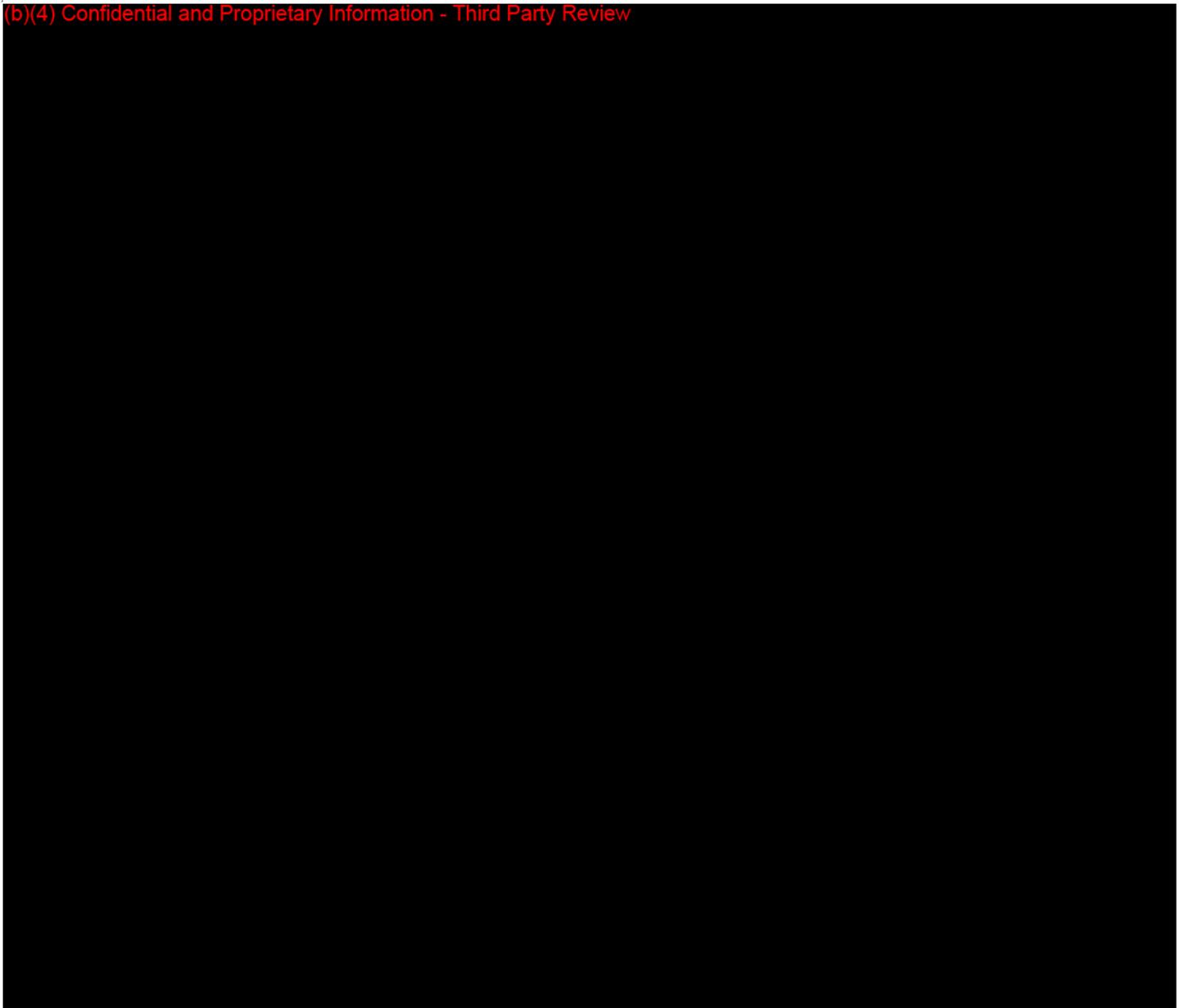


(b)(4) Confidential and Proprietary Information - Third Party Review



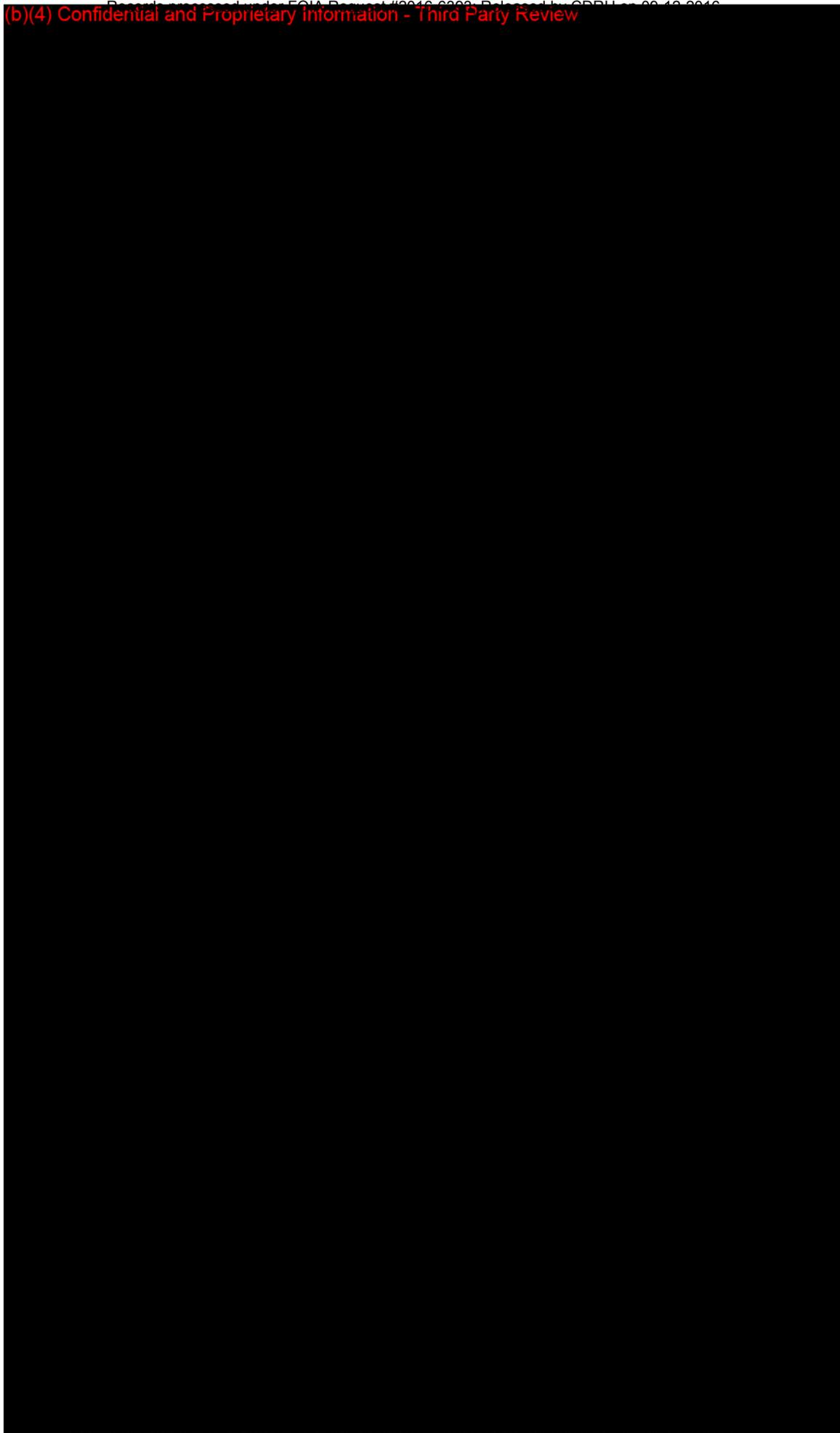
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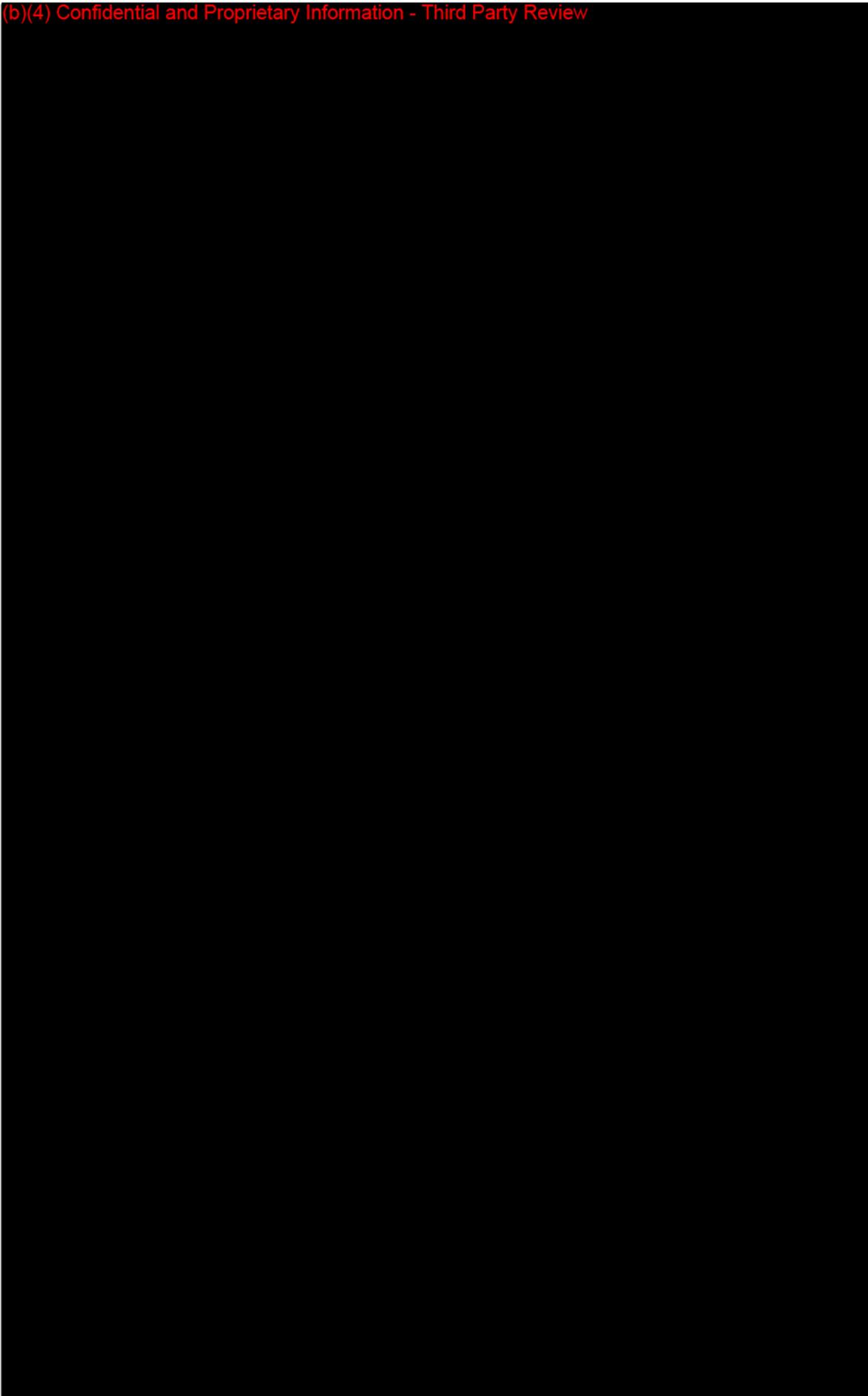
(b)(4) Confidential and Proprietary Information - Third Party Review

Attachment 11
Page 1/2



Attachment 11
Page 2/2

(b)(4) Confidential and Proprietary Information - Third Party Review



Conflict of Interest Statement

Company Name: Dynatherm Medical, Inc.
File Number: FD1099
Project Number: 04CA08550
Device: VitalHeat™
Date: February 18, 2004

The UL's staff identified below were involved with this Review. These personnel continue to meet the personnel qualifications and prevention of conflict of interest criteria established by UL in accordance with the FDA requirements for Third Party Reviewers.

To the best of our knowledge and belief, our Review statements are true and accurate. Our Review is based on the 510(k) that is submitted with our comment checklists as part of this package.

We understand that the submission of false information to the government is prohibited.

Reviewer
Signature



Morten Simon Christensen

Supervisor
Signature



Denise Leung Klinker

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Product Classification Database

Device System, Thermal Regulating
Device Description Thermal regulating system.
Medical Specialty Cardiovascular
Product Code DWJ
Regulation Number [870.5900](#)
Device Class 2
GMP Exempt? No
510(k) Exempt? No
Third Party Review *Eligible for Accredited Persons Expansion Pilot Program*
[Accredited Persons and Third Party Program Information](#)

Accredited Persons

- [California Department Of Health Services](#)
- [Citech](#)
- [Entela, Inc.](#)
- [Kema Quality B.V.](#)
- [Regulatory Technology Services, Llc](#)
- [Tuv America, Inc.](#)
- [Tuv Rheinland Of North America, Inc.](#)
- [Underwriters Laboratories, Inc.](#)

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

January 8, 2004

Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA. 94010

Attn: Mr. John Kane

Subject: Third Party Review of 510(k) for Temperature Disorder Device
Regulation Number 870.5900, Product Code DWJ

Dear Mr. Kane,

Thank you for your request of December 15, 2003 requesting UL to conduct the Subject Review of your 510(k) Premarket Notification submittal to the U.S. Food and Drug Administration (FDA).

THIRD PARTY REVIEW

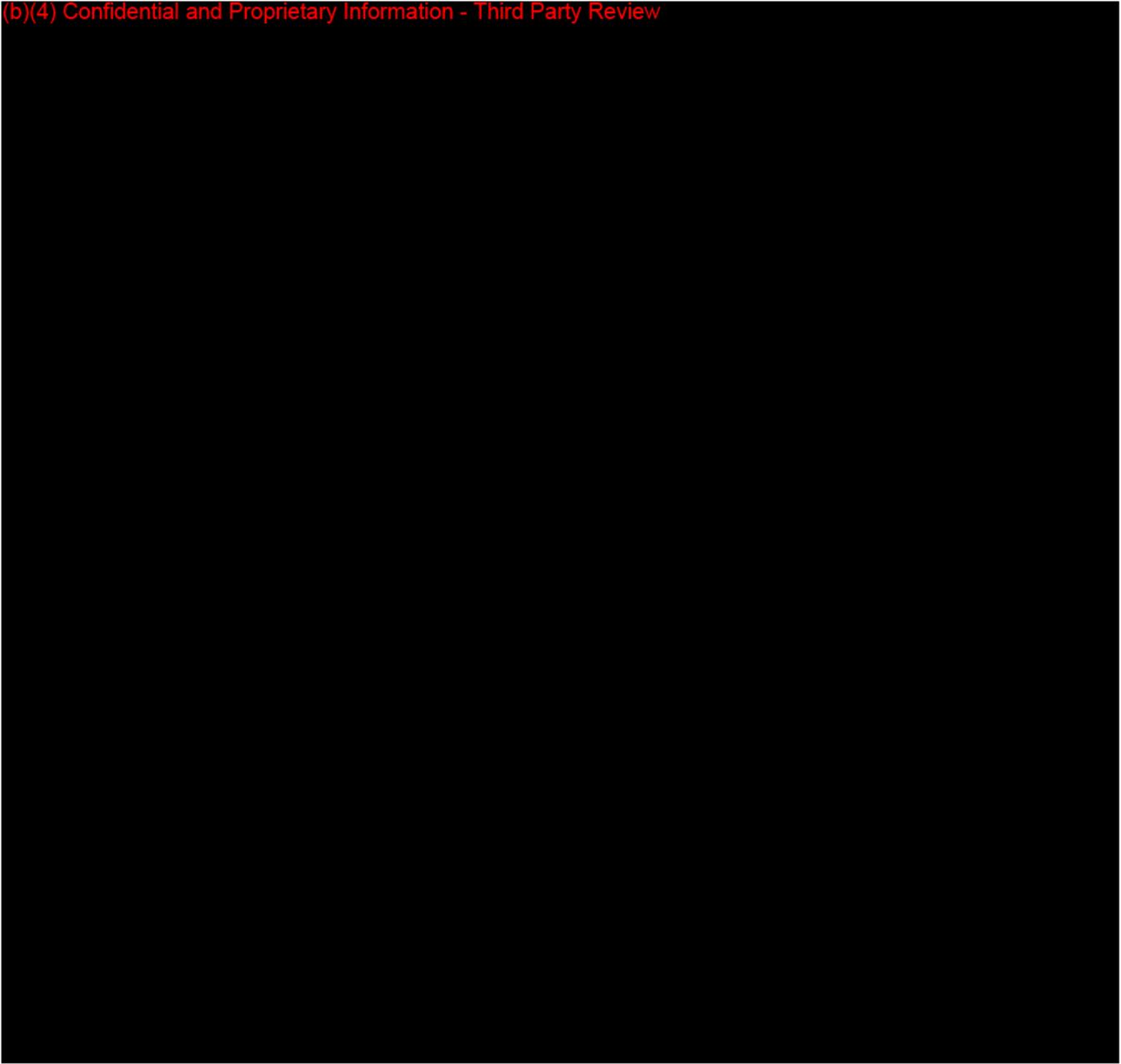
The sole purpose of this project is to review your 510(k) submittal and forward a recommendation of substantial equivalence or not substantially equivalent to the FDA Office of Device Evaluation (ODE).

(b)(4) Confidential and Proprietary Information - Third Party Review

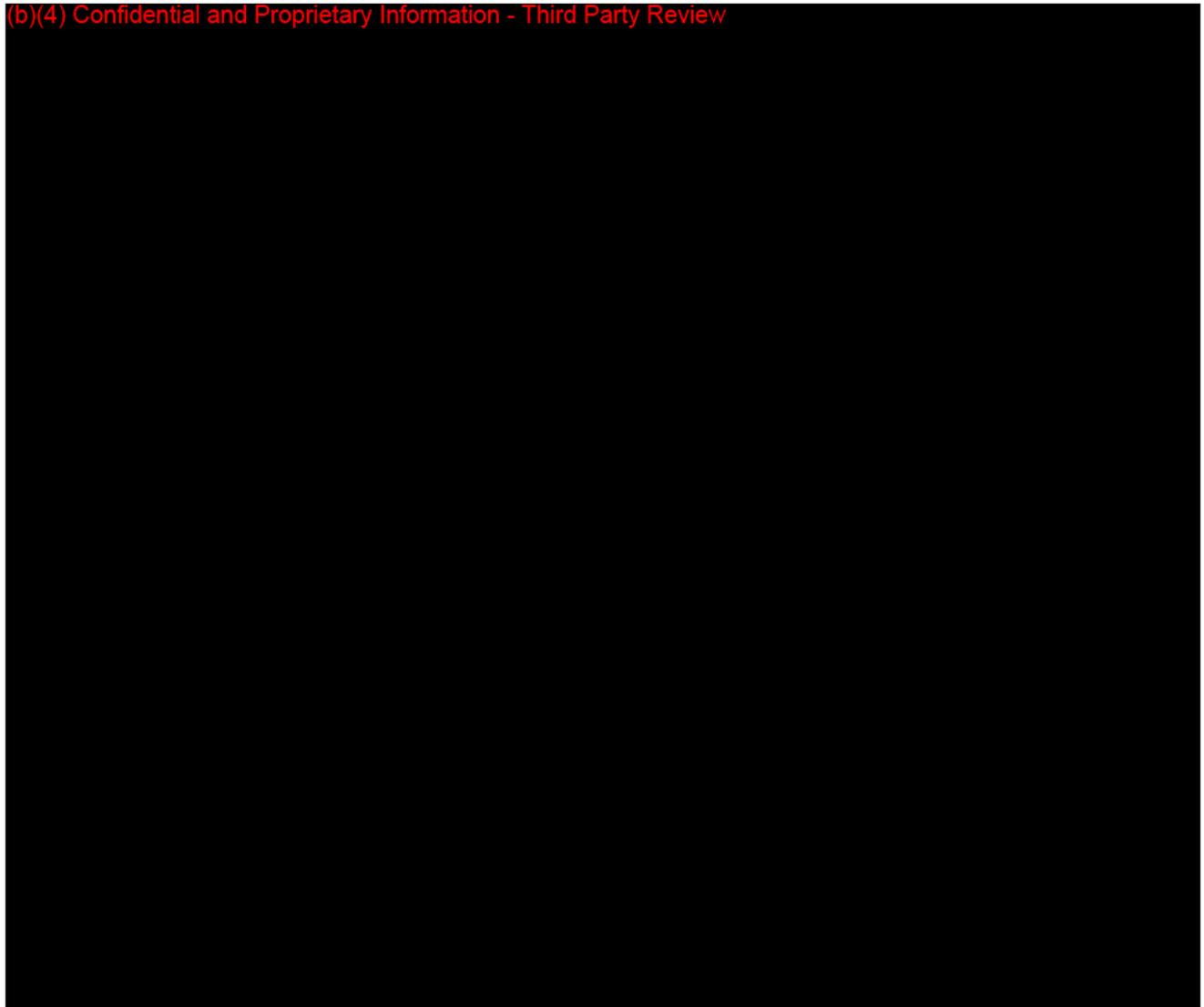


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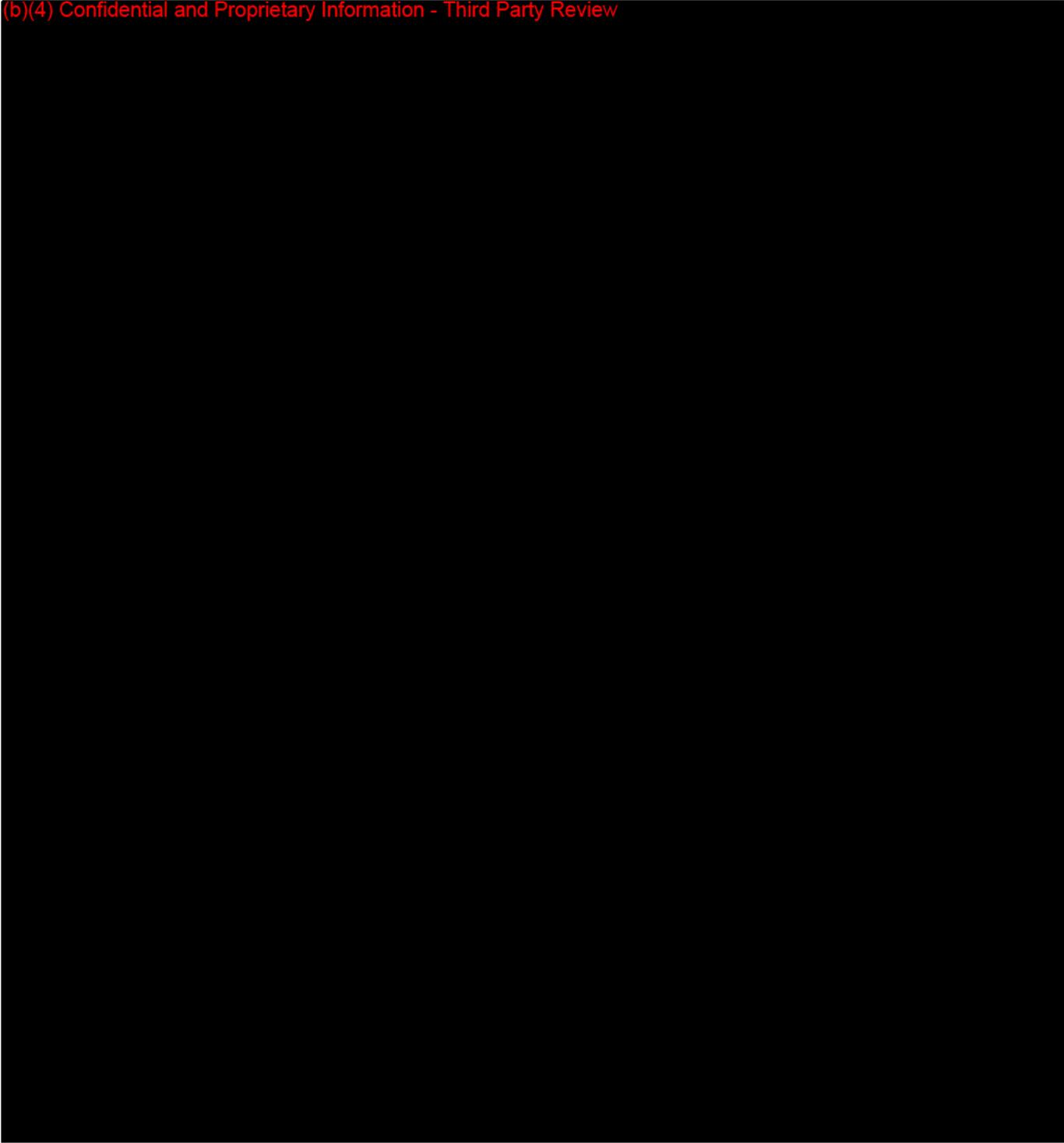
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Client Declaration and Authorization

(b)(4) Confidential and Proprietary Information - Third Party Review



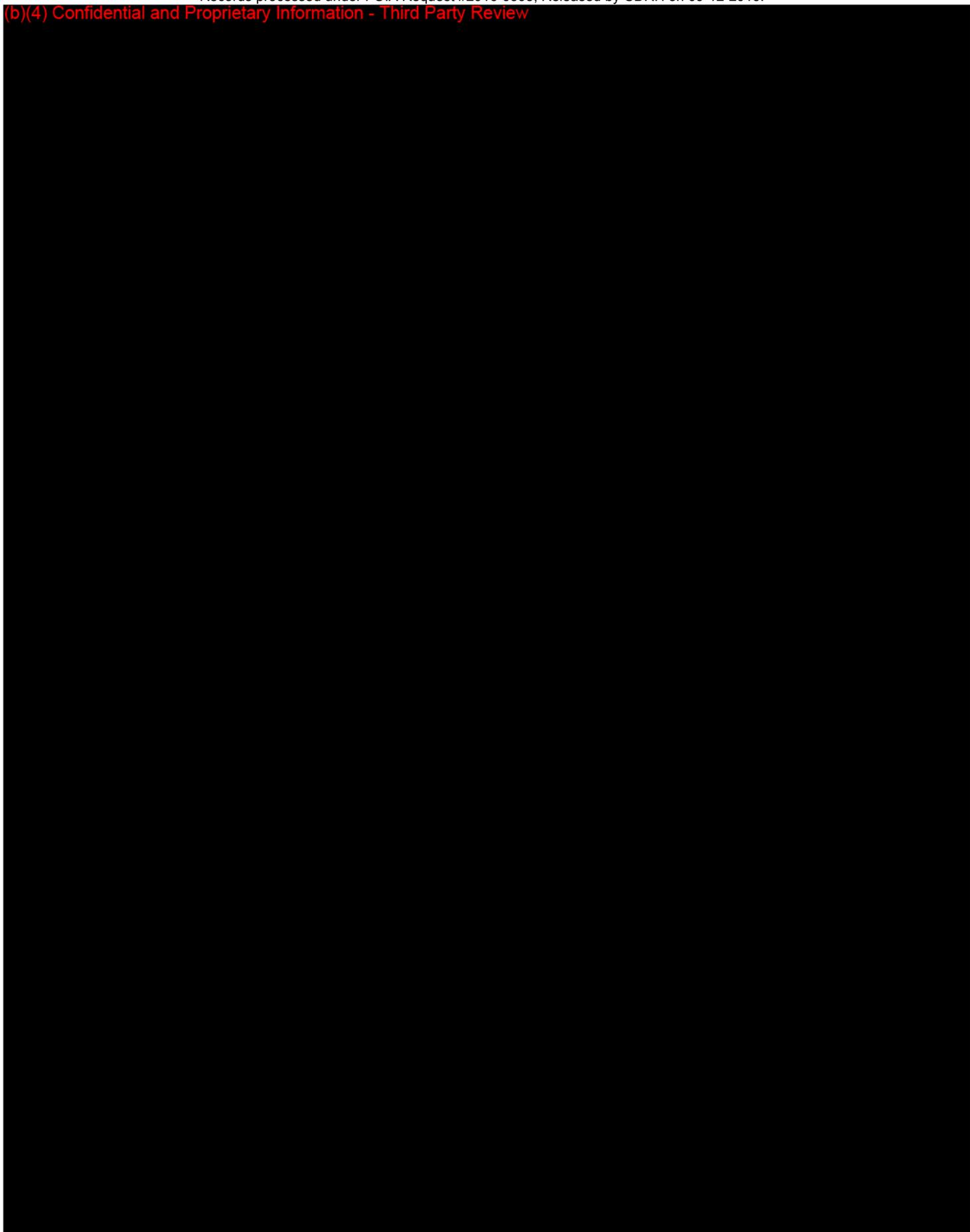
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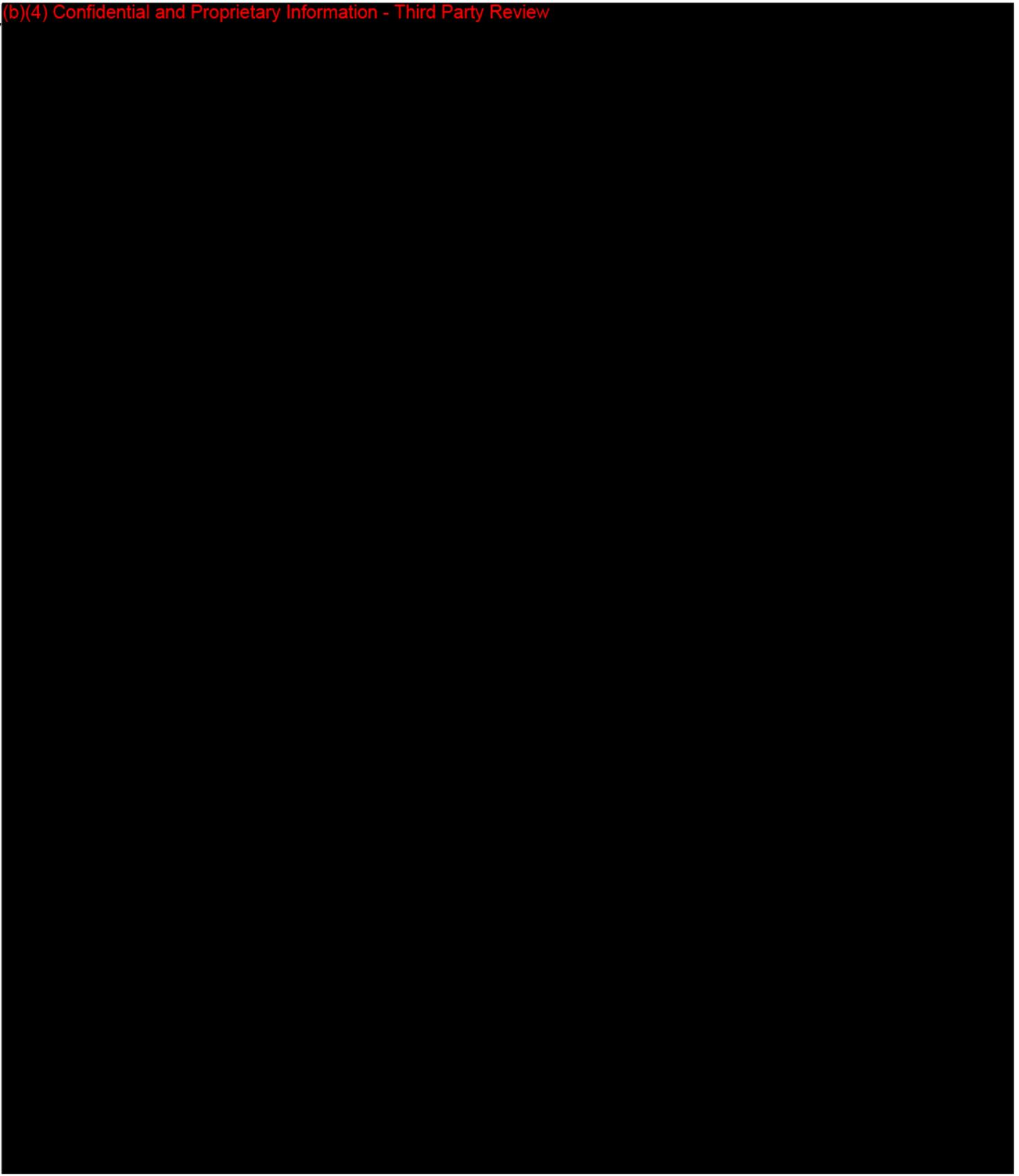
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510(k) Premarket Notification Database

Device Classification Name	System, Thermal Regulating
510(K) Number	K003368
Regulation Number	870.5900
Device Name	Acrotherm
Applicant	Aquarius Medical Corp. 16047 North 82nd St. Scottsdale, AZ 85260
Contact	Christina M Fleming
Product Code	DWJ
Date Received	10/30/2000
Decision Date	01/19/2001
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Cardiovascular
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

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K003368

Premarket Notification 510(k)

JAN 19 2001

AcroTherm

Section 2-Certifications and Summaries

Aquarius Medical Corporation

16047 North 82nd Street

Scottsdale, Arizona 85260

Non-Confidential Summary of Safety and Effectiveness

Page 1 of 3
27-Oct-00

Aquarius Medical Corporation, Inc.
16047 North 82nd Street
Scottsdale, Arizona 85260

Tel - (480) 991-1818

Fax - (480) 991-4335

Official Contact: Michael McCauley, President

Proprietary or Trade Name: AcroTherm

Common/Usual Name: AcroTherm

Classification Name: Thermal Regulating System

Device: AcroTherm

Predicate Devices: Aquarius Medical Corporation, Inc.
Thermo-STAT - K970367
MTRE Advanced Technology, Inc.
Allon 2001 - K001546

Device Description:

The Aquarius Medical Corporation's AcroTherm consists of the following elements:

- Warming chamber with tubing set
- Control Unit
- Tubing Set
- Disposable Arm Liner

The AcroTherm is a compact, portable thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand and forearm.) The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand & forearm), which should not impede standard patient care and/or full body access.

Indicated Use:

The AcroTherm is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

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Premarket Notification 510(k)

AcroTherm

Section 2-Certifications and Summaries

Aquarius Medical Corporation

16047 North 82nd Street

Scottsdale, Arizona 85260

Non-Confidential Summary of Safety and Effectiveness

Page 3 of 3
27-Oct-00

		Predicate	Predicate
	AQUARIUS MEDICAL CORPORATION	AQUARIUS MEDICAL CORPORATION	MTR
Product	AcroTherm	Thermo-Stat K970367	Allon 2001 K001546
Mobility	Hand-held	NA	4 wheels
Water Tank	450 – 500 ml	NA	6 Liter
Flow Rate	< 500 ml/min	NA	2-1.25L/min
Safety:			
High Temp Alarm	Yes	No	Yes
Water Level	Yes	NA	Yes
Chamber Sub-atmospheric pressure	Yes	Light	NA
Seal Pressure	Yes	Light	NA
Materials:			
Chamber	ABS	Polycarbonate	NA
Heating Pad	Urethane	PVC	
Disposable	Urethane	PVC	
Contraindications:	Patients under 18. Patients with peripheral vascular disease.	Patients under 18. Patients with peripheral vascular disease	Patients with open, widespread skin lesions that will contact the device or patients with multiple trauma

Differences between Other Legally Marketed Predicate Devices:

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicates.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2001

Aquarius Medical Corporation
c/o Mr. Mike McCauley
President
16099 North 82nd Street
Suite B-1
Scottsdale, AZ 85260

Re: K003368
Trade Name: AcroTherm™
Regulatory Class: II (two)
Product Code: DWJ
Dated: January 2, 2001
Received: January 4, 2001

Dear Mr. McCauley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

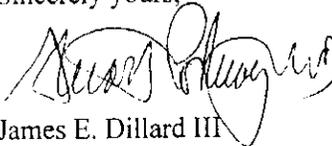
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Page 2 – Mr. Mike McCauley

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-5648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,


for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Premarket Notification 510(k)

AcroTherm

Section 2-Certifications and Summaries

2.3 Indications for Use

510(k) Number: K003368 (-To be assigned)

Device Name: AcroTherm

Intended Use: The AcroTherm is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Concurrence of CDRH, Office of Device Evaluation(ODE)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K003368


Division of Cardiovascular & Respiratory Devices
510(k) Number K003368

Prescription Use or Over-the-Counter Use
(Per CFR 801.109)

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[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)

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510(k) Premarket Notification Database

Device Classification Name	System, Thermal Regulating
510(K) Number	K970367
Regulation Number	870.5900
Device Name	Thermo-Stat System
Applicant	Aquarius Medical Corp. 7525 East Camelback Rd. Suite 210 Scottsdale, AZ 85251
Contact	W. Jeffrey Chandler
Product Code	DWJ
Date Received	01/31/1997
Decision Date	12/17/1997
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Cardiovascular
Statement/Summary/Purged Status	Summary/Purged 510(K)
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

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

DEC 17 1997

510(K) SUMMARY

TRADE NAME:

Thermo-STAT System

GENERIC NAME:

Body Core Thermoregulation System

CLASSIFICATION OF PERFORMANCE STANDARD:

The Food and Drug Administration has classified devices of this generic type into Class II, DWJ. To date, no performance standards have been established for devices of this type.

INTENDED USE:

The Thermo-STAT is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and a thermal load (heat) to a distal appendage.

DEVICE DESCRIPTION:

The Thermo-STAT is a non-invasive and portable body core warming device which provides a non-invasive technique to treat and prevent hypothermia. The Thermo-STAT's principle of action for counteracting hypothermia is to create a thermal pipeline between the skin and the body core. The Thermo-STAT functions by applying a combination of heat and pressure to only the distal aspect of an arm or leg. Using the Thermo-STAT, a thermal load is exchanged between the application site and the body core. Vasoconstriction in a hypothermic individual prevents superficial heat alone from effectively altering the body core temperature. The Thermo-STAT circumvents this "vasoconstrictive blockade" with a slight negative pressure (40-60mmHg) and enables a thermal load to be transferred directly and exclusively from a thermal heat pad to the body core via the bloodstream. Current means, such as forced air rewarming, fail to effectively overcome the "vasoconstrictive blockade."

PERFORMANCE DATA:

Sample devices were subjected to physical bench testing. Tests included current vacuum and heat cycle test, flow rate capabilities, and performance under simulated conditions. Based on these test results, it was concluded that the design and proper fabrication of that design offered a considerable safety margin with regard to simulated clinical use.

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HUMAN CLINICAL EVALUATION:

A clinical study was performed under a non-significant risk IDE to test and confirm the system's functionality and safety during non-invasive active rewarming of the body core temperature for hypothermic patients. A clinical evaluation was randomly performed on 22 patients undergoing a variety of general surgical procedures. These patients were observed hypothermic at the conclusion of their surgery and, therefore, the Thermo-STAT was employed to raise their body core temperature. The combination of negative pressure and thermal load was non-invasively applied to hypothermic patients' distal limb with their informed consent. A 2°C rise in body core temperature was observed in the first 10 minutes of application of the Thermo-STAT device. It was observed that there were no side effects to the patient from this treatment. The clinical tests resulted in the conclusion that negative pressure rewarming is a viable technique for rapidly rewarming patients in the PACU.

BIOCOMPATIBILITY TESTS OF MATERIALS:

Tests for biocompatibility of materials used in the fabrication of the Thermo-STAT were performed to establish that the materials used in the device meet the qualifications for short-term use non-invasively on the skin's surface. As a result of these tests, it was concluded that the materials met the qualifications for short term use non-invasively on the skin's surface.

STERILIZATION:

The Thermo-STAT is designed to be a non-sterile product.

PACKAGING:

The Thermo-STAT (seal and thermal fluid pad) is for single-use only and will be placed in a protective dispenser. A protective overshipper will be utilized for shipping.

Packaging was designed to protect the device from damage during processing, storage and distribution.

SUBSTANTIAL EQUIVALENCE:

The Thermo-STAT is equivalent in its intended use, as well as design, composition and function, to the rewarming devices legally marketed by Augustine Medical, MityVac and Prism Technologies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

Mr. W. Jeffrey Chandler
President and CEO
Aquarius Medical Corporation
16099 North 82nd Street
Suite B-1
Scottsdale, AZ 85260

DEC 17 1997

Re: K970367
Thermo-STAT™ System
Regulatory Class: II (Two)
Product Code: DWJ
Dated: September 26, 1997
Received: September 26, 1997

Dear Mr. Chandler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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Page 2 - Mr. W. Jeffrey Chandler

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

145

510(k) Number (if known): K 970367

Device Name: Thermo-STAT™ System

Indication for Use: The Thermo-STAT is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and a thermal load (heat) to a distal appendage.

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

Concurrence of DCRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K 970367

Prescription Use
(Per 21 CFR 801.109)

OR

Over the Counter Use

46



"John"
<john@dynathermmedical.com>

04/05/2004 03:24 PM

To <Morten.S.Christensen@us.ul.com>

cc

bcc

Subject

Hi Morten: updates

Take care,



John SECTION 5.0 PREMARKET 510(K).doc

147

Premarket Notification 510(k)
Section 5 – Comparison to Predicates

VitalHeat™

5.0	Comparison to Predicates
5.1	Discussion of the Comparison and Differences
5.2	Substantial Equivalence
5.3	Predicate Information
Table 5.01	Comparative Table

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Premarket Notification 510(k)
Section 5 – Comparison to Predicates

VitalHeat™

5.1 Discussion of the Comparison and Differences

The VitalHeat™ is a modification of a 510(k) cleared thermal regulating system, the AcroTherm™ K003365. The modified device utilizes a circulating water paddle system, similar to the systems of other devices in this classification. **Table 5.01** summarizes the major elements of comparison for the modified device and the two predicate devices.

The VitalHeat™, like the AcroTherm™, applies a combination of heat and sub-atmospheric pressure to a distal limb. Both devices have the limb and heat source enclosed in a mitt. The main difference between the VitalHeat™ and the AcroTherm™ is the heat source; supplies heat through a water perfusion pad, which maintains a constant temperature within a specified range. The temperature range of both devices is the same. In addition, The VitalHeat™ has a separate control unit and connecting hoses to supply the heated water and sub-atmospheric pressure to the mitt.

The VitalHeat™ system has similar but improved design differences between the predicates. AcroTherm™ used an open water loop system, the water was added to the tank thru a removable cap on the control unit. The heated water flowed thru the tubing to the warming chamber. Inside the chamber were two (2) water perfusion pads, in contact to the patients hand and forearm both top and bottom. The warming mitt was also detachable from the tubing set thru a connector. We found thru clinicals and customer interface that filling the system with water and keeping it clean was difficult.

VitalHeat™ is a closed loop system water is added at the factory and unit is shipped to the customer filled. Unlike AcroTherm™ The VitalHeat™ uses just palm side of the hand. The heated water is an aluminum paddle heatsink. The design of this heatsink is shaped to provide maximum hand contact. This design proved during testing to increase heat transfer over AcroTherm™ type water perfusion pads.

Hands vs. Distal Limb

The palm of your hands and feet are the heat exchangers of the body. The current design provides better heat transfer from heat source to the hand. Thru testing we found the palm of the hand was all that is needed to provide a change in patients temperature.

Water Tank 200ML vs. 400 – 500 ML

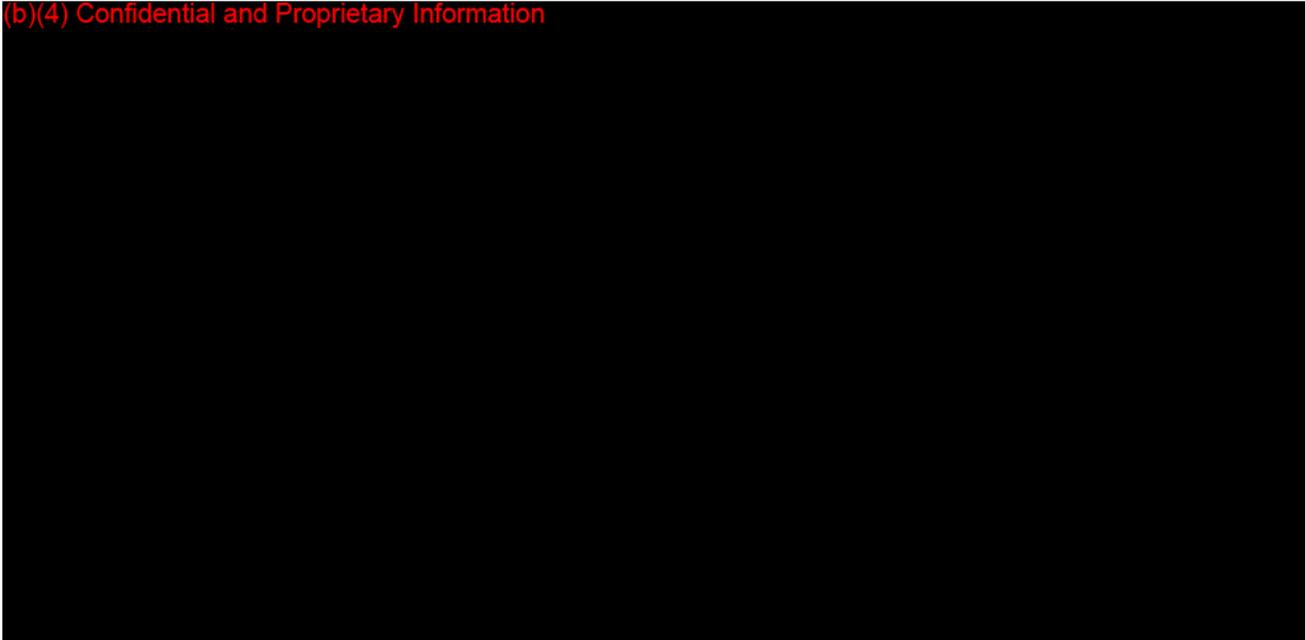
The Volume of water was reduced in the tank; do to the change from water perfusion pads to the domed paddle in The VitalHeat™.

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Flow Rate > 1000 MI/Min. vs. < 500 MI/Min

The flow rate was increased to 1000 MI/Min. to enhance thermal response of the temperature control loop.

(b)(4) Confidential and Proprietary Information



The VitalHeat™ is a modification of an existing approved device using the technology of another existing approved device in the same classification.

5.2 Substantial Equivalence

The VitalHeat™ is viewed as substantially equivalent to the predicate devices since it:

1. Has the same intended uses:
 - The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by warming their body core. This accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.
2. Has the same environments for use:
 - Hospital/Healthcare environments where patient temperature management is necessary.

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Premarket Notification 510(k)
Section 5 – Comparison to Predicates

VitalHeat™

3. Has design features present in both predicates:

- Warming Mitt – AcroTherm™
- Water perfusion pad – AcroTherm™
- Separate control panel for control and monitoring of the system – AcroTherm™
- Warming Mitt which applies heat and sub-atmospheric pressure simultaneously – AcroTherm™
- Uses heated water as a thermal medium for application of heat through the thermal pad – AcroTherm™

4. Is made of similar materials:

- All patient contacting materials are biocompatible and have passed USP Class VI testing.

5.3 Predicate Information

TAB #15 and TAB #16 contains information on the two predicate devices.

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**Premarket Notification 510(k)
Section 5 – Comparison to Predicates**

VitalHeat™

Table 5.01 Comparative Table

Product Features and Benefits

Features	Benefits
<ul style="list-style-type: none"> Product is applied to hand appendage 	<ul style="list-style-type: none"> Maximizes patient access and ability to perform standard care of patient.
<ul style="list-style-type: none"> Easy 5 steps 	<ul style="list-style-type: none"> One Size Preprogrammed functions; one button activates system Quick set up
<ul style="list-style-type: none"> Combination with water perfusion pad Combination of vacuum and heated water thermal exchange paddle. 	<ul style="list-style-type: none"> Maintain temperature in OR and warm up in PACU.
<ul style="list-style-type: none"> Cover 95% human anatomical size. 	<ul style="list-style-type: none"> One size fits all
<ul style="list-style-type: none"> Multiple automatic shut-off systems for increase patient safety. 	<ul style="list-style-type: none"> Temperature, pressure monitored and incorporate alarms for improper functioning
<ul style="list-style-type: none"> Easy to read indicators 	<ul style="list-style-type: none"> Increase product efficacy
<ul style="list-style-type: none"> Blown hot air on entire body vs. warm up on hand 	<ul style="list-style-type: none"> Reduce uncomfortable convection hot air
<ul style="list-style-type: none"> Pre-op and Intra-op use 	<ul style="list-style-type: none"> Keep warm during peri operative procedure
<ul style="list-style-type: none"> Small disposable 	<ul style="list-style-type: none"> Cost saving
<ul style="list-style-type: none"> Low cost and easy to apply disposable 	<ul style="list-style-type: none"> Cost and time save
<ul style="list-style-type: none"> Provides efficient heat transfer using water perfusion heat paddle. 	<ul style="list-style-type: none"> Maximizes heat transfer area of the body to deliver heat to the core
<ul style="list-style-type: none"> Closed water circulation system 	<ul style="list-style-type: none"> Limited water refilling and maintenance needed
<ul style="list-style-type: none"> Easy to connect the control unit to an IV pole or a wall mount 	<ul style="list-style-type: none"> Goes with the patient during transport

152



"John"
<john@dynathermmedical.com>

03/30/2004 04:30 PM

To <Morten.S.Christensen@us.ul.com>
cc
bcc
Subject

Hi Morten: updates so far.

Take care,



John Kane updates.doc

153

**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.1 Summary of Safety and Effectiveness

Indicated Used:

The VitalHeat™ designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to hand.

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
Non-Confidential Summary of Safety and Effectiveness
Page 2 of 3**

Patient Population:

The system is for use with patients experiencing cold who are 18 years of age and older.

Environments of Use:

The device is intended for use throughout healthcare facilities.

Contraindications:

The VitalHeat™ is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

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Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

Page 3 of 3
510 (k) COMPARATIVE TABLE

COMPANY	DYNATHERM	AMC	AMC
PRODUCTS	VitalHeat™	ACROTHERM K003368	THERMO-STAT K970367
Intended use	Patient Temperature Control and Maintain	Patient Temperature Control and Maintain	Patient Temperature Control
Intended Environment of use	Healthcare Facilities	Healthcare Facilities	PACU
Contraindications	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease
Type	Sub Atmospheric Pressure/Water Paddle Disposable Mitt	Sub Atmospheric Pressure/Water Perfusion Pad in Camber	Negative Pressure/ Thermal Pad in Chamber
Pressure Device	Yes – Neg.	Yes – Neg.	Yes – Neg.
Sub-Atmospheric Pressure (mmHg)	40 ± 5 mmHg	40 ± 5 mmHg	40 – 60 mmHg
Electrical (AC)	Yes	Yes	No
Temperature Range	≤ 45 ° C	≤ 45 ° C	≤ 45 ° C
Application Site	Hand	Distal Limb	Distal Limb
Control System			
Control Type	Micro - Logic	Micro - Logic	N/A
Size - Controller	16 x 6 x 6 In.	14 x 6 x 5 In.	N/A
Weight	15.0 Lbs.	9.30 Lbs.	N/A
Mobility	Hand-Held IV Pole MTG Table Top	Hand-Held IV Pole MTG Table Top	N/A
Water Tank	200 ml	400 – 500 ml	N/A
Flow Rate	> 1000 ml/Min.	< 500 ml/Min.	N/A
Safety			
High Temperature Alarm	Yes	Yes	No
Water Level	Yes – Water Flow	Yes	N/A
Sub-Atmospheric Pressure	Yes LED and Audible	Yes LED and Audible	Yes LED Only
Timer	Yes	No	No
Seal	Yes	Yes	N/A

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Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
Non-Confidential Summary of Safety and Effectiveness
Page 1 of 3**

Dynatherm Medical, Inc.	Phone: (650) 777-4361
	Fax: (650) 777-4370
Official Contact:	Nathan Hamilton
Proprietary or Trade Name:	VitalHeat™
Common/Usual Name:	VitalHeat™
Classification Name:	Thermal Regulating System
Predicate Device:	Aquarius Medical Corporation Thermo-STAT – K970367 Aquarius Medical Corporation AcroTherm – K003368

Device Description:

The Dynatherm Medical, Inc. VitalHeat™

- Warming Mitt
- Control Unit

The VitalHeat™ is a compact, thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand). The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand), which should not impede standard patient care and/o full body access.

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Premarket Notification 510(k)
Section 5 – Comparison to Predicates

VitalHeat™

1. Has design features present in both predicates:

- Warming Mitt – AcroTherm
- Water perfusion pad – AcroTherm
- Separate control panel for control and monitoring of the system – AcroTherm
- Warming Mitt which applies heat and sub-atmospheric pressure simultaneously – AcroTherm
- Uses heated water as a thermal medium for application of heat through the thermal pad – AcroTherm

2. Is made of similar materials:

- All patient contacting materials are biocompatible and have passed USP Class VI testing.

5.3 Predicate Information

TAB #15 and TAB #16 contains information on the two predicate devices.

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**Premarket Notification 510(k)
Section 6 – Biocompatibility and Materials**

VitalHeat™

BIOCOMPATIBILITY

All the materials utilized in construction of the VitalHeat™ device are commonly utilized in medical devices. Any material which has potential for extended or intimate patient contact is biocompatibility and has passed USP Class VI plastics testing. See section 4.11 (and Table below) for a listing of components and their material composition.

Location	Component	Material	Patient Contact	Evaluation
Disposable	Mitt, Lower Mitt, Upper	(b)(4) Confidential and Proprietary Information		
Heating Paddle	Heating Dome			
Disposable	Diaphragm, Mitt			
Disposable	Gasket, Mitt/Paddle Interface			
Disposable	Vacuum Cord Gasket			
Disposable	Hand Strap Assembly, Mitt			
Disposable	Mitt Hinge			
Disposable	Mitt Filter Assembly			
Disposable	Mitt Bag – 10 x 12 Mitt Package Label			
Disposable	Product ID Label			
Disposable	Mitt IFU Protective Sheet			
Disposable	Seal Assembly			
Tubing Set	Outer Insulation			
	Inner Tubing			
Control Unit	Housing			

Device Certification

The polyurethane materials that will come into direct contact with the patient have passed USP Class VI plastics testing as certified by the vendor.

* Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
Same Material as Acrotherm Device **K003368**

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Indications for Use

510(k) Number (if known):

Device Name: VitalHeat™

Indications For Use:

The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by warming their body core. This accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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 _____

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**Premarket Notification 510(k)
Section 1 – General Information**

VitalHeat™

1.0 General Information

- 1.1 Establishment Name: Dynatherm Medical Corporation
819 Mitten Road
Suite 42
Burlingame, CA 94010
- 1.2 Establishment Number:
- 1.3 Official Correspondent: John R. Kane
- 1.4 Device Name: VitalHeat™
- 1.5 Classification: Class II
- 1.6 Classification Reference: 21 CFR 870.5900
- 1.7 FDA Classification Code: DWJ
- 1.8 Classification Panel: Cardiovascular Panel
- 1.9 Classification Name: Thermal Regulating System
- 1.10 Reason for Submission: Modification to a device cleared under K003368
- 1.11 Predicate Devices: Aquarius Medical Corporation, Inc.
Thermo-STAT – K970367
Cleared December 17, 1997
- Aquarius Medical Corporation
Acro Therm – K003368
Cleared January 19, 2001
- 1.12 Performance Standards: None applicable under Section 514
- 1.13 Intended Use: The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by warming their body core. This accomplished with local application of negative pressure and thermal load (heat) to a distal appendage



"John"
<john@dynathermmmedical.com>

03/30/2004 04:30 PM

To <Morten.S.Christensen@us.ul.com>
cc
bcc
Subject

Hi Morten: Here are the predicate 510 K

Take care,



John k003368.pdf



k970367.pdf

161

K003368

JAN 19 2001

Premarket Notification 510(k)

AcroTherm

Section 2-Certifications and Summaries

Aquarius Medical Corporation

16047 North 82nd Street

Scottsdale, Arizona 85260

Non-Confidential Summary of Safety and Effectiveness

Page 1 of 3
27-Oct-00

Aquarius Medical Corporation, Inc.
16047 North 82nd Street
Scottsdale, Arizona 85260

Tel - (480) 991-1818

Fax - (480) 991-4335

Official Contact: Michael McCauley, President

Proprietary or Trade Name: AcroTherm

Common/Usual Name: AcroTherm

Classification Name: Thermal Regulating System

Device: AcroTherm

Predicate Devices: Aquarius Medical Corporation, Inc.
Thermo-STAT - K970367
MTRE Advanced Technology, Inc.
Allon 2001 - K001546

Device Description:

The Aquarius Medical Corporation's AcroTherm consists of the following elements:

- Warming chamber with tubing set
- Control Unit
- Tubing Set
- Disposable Arm Liner

The AcroTherm is a compact, portable thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand and forearm.) The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand & forearm), which should not impede standard patient care and/or full body access.

Indicated Use:

The AcroTherm is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

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Premarket Notification 510(k)

AcroTherm

Section 2-Certifications and Summaries

Aquarius Medical Corporation

16047 North 82nd Street

Scottsdale, Arizona 85260

Non-Confidential Summary of Safety and Effectiveness

Page 2 of 3
27-Oct-00

Patient Population:

The system is for use with patients experiencing cold who are 18 years of age and older.

Environments of Use:

The device is intended for use throughout healthcare facilities.

Contraindications:

The AcroTherm is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

	Predicate	Predicate	Predicate
	AQUARIUS MEDICAL CORPORATION	AQUARIUS MEDICAL CORPORATION	MTRE
Product	AcroTherm	Thermo-Stat K970367	Allon 2001 K001546
Intended Use	Patient Temp. Control Hypothermia	Patient Temp. Control Hypothermia	Patient Temp. Control Hypo/hyperthermia
Intended Population	Adult patients	Adult patients	Adult and pediatric patients
Prescription Device Only	Yes	Yes	Yes
Use Environment	Hospitals and healthcare facilities	Hospital	Hospital
Design Features			
Type	Neg Pressure/ Water Perf Pad ✓	Neg Pressure/ Therm Pad	Hot Water Perfusion Pad
Pressure Device	Yes-neg 40±5	Yes-neg 40-60	No NA
Sub-atmospheric pressure (mmHg)	40±5	40-60	NA
Electric (AC)	Yes	No	Yes
Temp. Range	≤45 °C	≤45 °C	≤40.2 °C
Application Site	Distal-Limb	Distal-Limb	Up to Whole Body
Disposable Type	Limb Cover	Thermal Pad/Seal	Perfusion Pad
Control System			
Controller Type	Micro-logic	NA	Micro-Processor
Size	14x6x5in	NA	103x21x20in
Weight	<5lb	NA	73lb

ATM = 760 mmHg

760
-720
40 mmHg

760
-40
720

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Premarket Notification 510(k)

AcroTherm

Section 2-Certifications and Summaries

Aquarius Medical Corporation

16047 North 82nd Street

Scottsdale, Arizona 85260

Non-Confidential Summary of Safety and Effectiveness

Page 3 of 3
27-Oct-00

		Predicate	Predicate
	AQUARIUS MEDICAL CORPORATION	AQUARIUS MEDICAL CORPORATION	MITRE
Product	AcroTherm	Thermo-Stat K970367	Allon 2001 K001546
Mobility	Hand-held	NA	4 wheels
Water Tank	450 – 500 ml	NA	6 Liter
Flow Rate	< 500 ml/min	NA	.2-1.25L/min
Safety			
High Temp Alarm	Yes	No	Yes
Water Level	Yes	NA	Yes
Chamber Sub-atmospheric pressure	Yes	Light	NA
Seal Pressure	Yes	Light	NA
Materials			
Chamber	ABS	Polycarbonate	NA
Heating Pad	Urethane	PVC	
Disposable	Urethane	PVC	
Contraindications	Patients under 18. Patients with peripheral vascular disease.	Patients under 18. Patients with peripheral vascular disease	Patients with open, widespread skin lesions that will contact the device or patients with multiple trauma

Differences between Other Legally Marketed Predicate Devices:

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicates.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2001

Aquarius Medical Corporation
c/o Mr. Mike McCauley
President
16099 North 82nd Street
Suite B-1
Scottsdale, AZ 85260

Re: K003368
Trade Name: AcroTherm™
Regulatory Class: II (two)
Product Code: DWJ
Dated: January 2, 2001
Received: January 4, 2001

Dear Mr. McCauley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

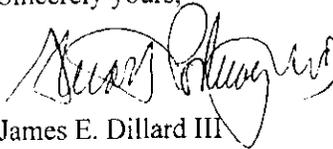
165

Page 2 – Mr. Mike McCauley

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-5648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,


for James E. Dillard III

Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

166

Premarket Notification 510(k)

AcroTherm

Section 2-Certifications and Summaries

2.3 Indications for Use

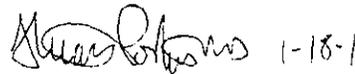
510(k) Number: K003368 (-To be assigned)

Device Name: AcroTherm

Intended Use: The AcroTherm is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Concurrence of CDRH, Office of Device Evaluation(ODE)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 003368

 1-18-1
Division of Cardiovascular & Respiratory Devices
510(k) Number K003368

Prescription Use or Over-the-Counter Use
(Per CFR 801.109)

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DEC 17 1997

510(K) SUMMARY

TRADE NAME:

Thermo-STAT System

GENERIC NAME:

Body Core Thermoregulation System

CLASSIFICATION OF PERFORMANCE STANDARD:

The Food and Drug Administration has classified devices of this generic type into Class II, DWJ. To date, no performance standards have been established for devices of this type.

INTENDED USE:

The Thermo-STAT is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and a thermal load (heat) to a distal appendage.

DEVICE DESCRIPTION:

The Thermo-STAT is a non-invasive and portable body core warming device which provides a non-invasive technique to treat and prevent hypothermia. The Thermo-STAT's principle of action for counteracting hypothermia is to create a thermal pipeline between the skin and the body core. The Thermo-STAT functions by applying a combination of heat and pressure to only the distal aspect of an arm or leg. Using the Thermo-STAT, a thermal load is exchanged between the application site and the body core. Vasoconstriction in a hypothermic individual prevents superficial heat alone from effectively altering the body core temperature. The Thermo-STAT circumvents this "vasoconstrictive blockade" with a slight negative pressure (40-60mmHg) and enables a thermal load to be transferred directly and exclusively from a thermal heat pad to the body core via the bloodstream. Current means, such as forced air rewarming, fail to effectively overcome the "vasoconstrictive blockade."

PERFORMANCE DATA:

Sample devices were subjected to physical bench testing. Tests included current vacuum and heat cycle test, flow rate capabilities, and performance under simulated conditions. Based on these test results, it was concluded that the design and proper fabrication of that design offered a considerable safety margin with regard to simulated clinical use.

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HUMAN CLINICAL EVALUATION:

A clinical study was performed under a non-significant risk IDE to test and confirm the system's functionality and safety during non-invasive active rewarming of the body core temperature for hypothermic patients. A clinical evaluation was randomly performed on 22 patients undergoing a variety of general surgical procedures. These patients were observed hypothermic at the conclusion of their surgery and, therefore, the Thermo-STAT was employed to raise their body core temperature. The combination of negative pressure and thermal load was non-invasively applied to hypothermic patients' distal limb with their informed consent. A 2°C rise in body core temperature was observed in the first 10 minutes of application of the Thermo-STAT device. It was observed that there were no side effects to the patient from this treatment. The clinical tests resulted in the conclusion that negative pressure rewarming is a viable technique for rapidly rewarming patients in the PACU.

BIOCOMPATIBILITY TESTS OF MATERIALS:

Tests for biocompatibility of materials used in the fabrication of the Thermo-STAT were performed to establish that the materials used in the device meet the qualifications for short-term use non-invasively on the skin's surface. As a result of these tests, it was concluded that the materials met the qualifications for short term use non-invasively on the skin's surface.

STERILIZATION:

The Thermo-STAT is designed to be a non-sterile product.

PACKAGING:

The Thermo-STAT (seal and thermal fluid pad) is for single-use only and will be placed in a protective dispenser. A protective overshipper will be utilized for shipping.

Packaging was designed to protect the device from damage during processing, storage and distribution.

SUBSTANTIAL EQUIVALENCE:

The Thermo-STAT is equivalent in its intended use, as well as design, composition and function, to the rewarming devices legally marketed by Augustine Medical, MityVac and Prism Technologies.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

Mr. W. Jeffrey Chandler
President and CEO
Aquarius Medical Corporation
16099 North 82nd Street
Suite B-1
Scottsdale, AZ 85260

DEC 17 1997

Re: K970367
Thermo-STAT™ System
Regulatory Class: II (Two)
Product Code: DWJ
Dated: September 26, 1997
Received: September 26, 1997

Dear Mr. Chandler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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Page 2 - Mr. W. Jeffrey Chandler

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K 970367

Device Name: Thermo-STAT™ System

Indication for Use: The Thermo-STAT is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and a thermal load (heat) to a distal appendage.

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

Concurrence of DCRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K 970367

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over the Counter Use _____

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**Morten S.
Christensen/SCL/ULI**
03/29/2004 02:42 PM

To john@dynathermmedical.com
cc
bcc
Subject 510(k) Review - VitalHeat

Hello John,

We have completed our review of the above referenced submission.

The following are our comments. The Checklist Question Number in the table corresponds to the "Third party Premarket Notification 510(K) Checklist for Acceptance Decision" and guidance documents specified. The referenced section numbers correspond to the ones in your 510(K) submission.

I will, of course, continue working on the review memo for this submission.

You are welcome to email the revised pages to me, however, please only include revised pages and make sure that page numbering is still accurate.

Please do not hesitate to contact me if you have any questions. Please respond at your earliest convenience.

Best Regards,



Attachment 5_Record of Deficiencies.doc

MORTEN SIMON CHRISTENSEN
Staff Engineer & FDA Office Coordinator
Medical Devices Conformity Assessment Services

Ph: (408) 876-2016
Fx: (408) 556-6218

Please click <http://www.ul.com/medical> for information about our services

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Record of Deficiencies

Company Name: Dynatherm Medical
File Number: FD1099
Project Number: 04CA08550
Device: VitalHeat™

Checklist Question Number	Describe in detail the additional information that is required.
	(b)(4) Confidential and Proprietary Information
4, 5	
Intended Use	
8	

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9	(b)(4) Confidential and Proprietary Information
15, 21	

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"Fleischer, Dina J."
<DJF@CDRH.FDA.GOV
>

03/16/2004 12:22 PM

To: "Morten.S.Christensen@us.ul.com"
<Morten.S.Christensen@us.ul.com>
cc: "Letzing, William G." <WGL@CDRH.FDA.GOV>
Subject: RE: Review Plan for 870.5900 [DWJ]

Hello Mr. Christensen,

Myself and lead reviewer Dr. Bill Letzing took a look at your review plan. I think it seems reasonable, however, I wanted to relay a few comments from Dr. Letzing. Specifically:

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

From: Letzing, William G.

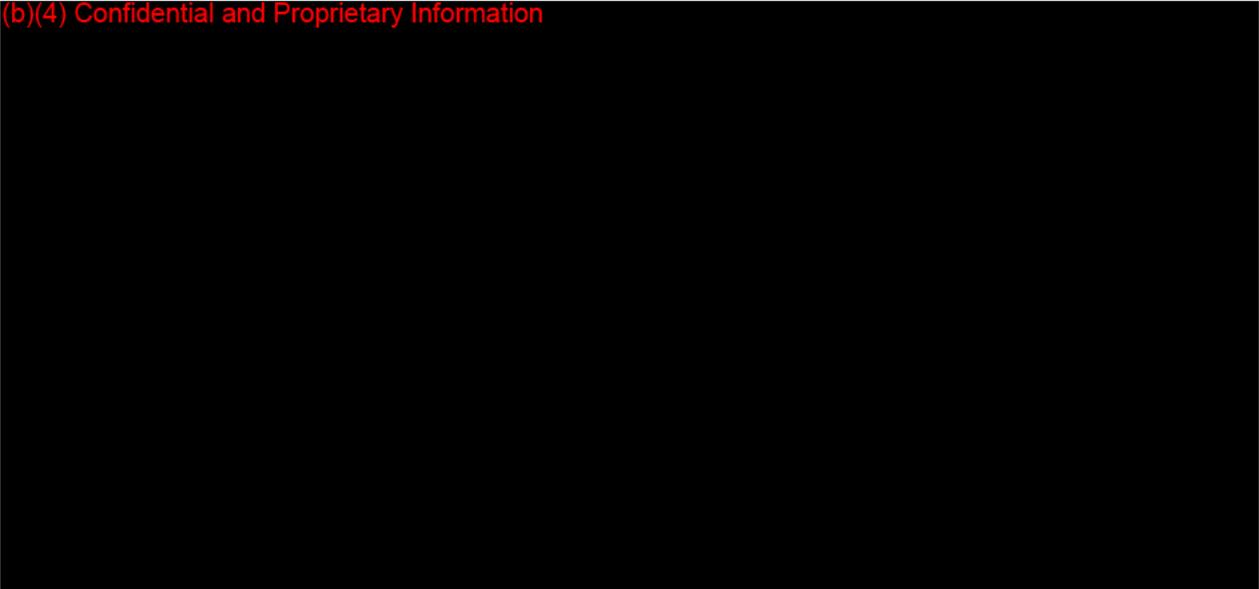
Sent: Tuesday, March 02, 2004 3:36 PM

To: Fleischer, Dina J.

Subject: RE: Review Plan for 870.5900 [DWJ]

Dina,

(b)(4) Confidential and Proprietary Information



Bill

Please let me know if you need anything else. So sorry for the delay in responding to your inquiry.

Best Regards,

Dina J. Fleischer

Branch Chief

Circulatory Support and Prosthetic Devices Branch

(301) 443-8517 x176

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN

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

From: Morten.S.Christensen@us.ul.com [mailto:Morten.S.Christensen@us.ul.com]

Sent: Monday, February 23, 2004 6:19 PM

To: DJF@CDRH.FDA.GOV

Subject: Review Plan for 870.5900 [DWJ]

Dear Mrs. Dina Fleischer,

(b)(4) Confidential and Proprietary Information



Proposed review plan:

(See attached file: Review Plan.doc)

Device information: 510(k) Summary(includes abbreviated device description and intended use), and indications for use statement

(See attached file: SECTION 2.0 PREMARKET 510(K).doc)

Detailed device description:

(See attached file: SECTION 4.0 PREMARKET 510(K)1.doc)

We look forward to receiving comments to the proposed review plan. If more information, or clarification is needed please do not hesitate to contact me.

Thank you.

MORTEN SIMON CHRISTENSEN
Staff Engineer & FDA Office Coordinator
Medical Devices Conformity Assessment Services

Phone: (408) 876-2016

Fax: (408) 556-6218

Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, CA 95050

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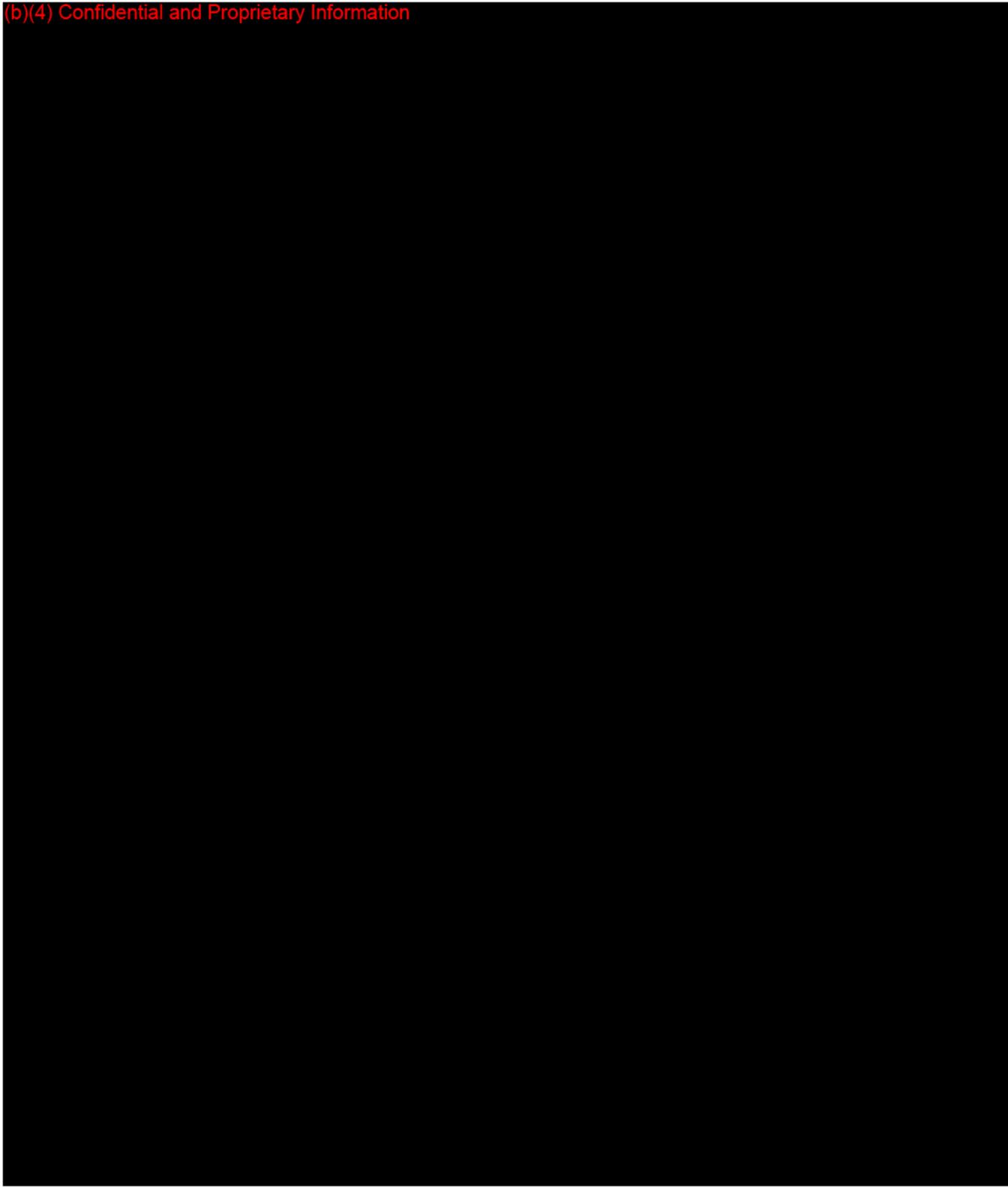
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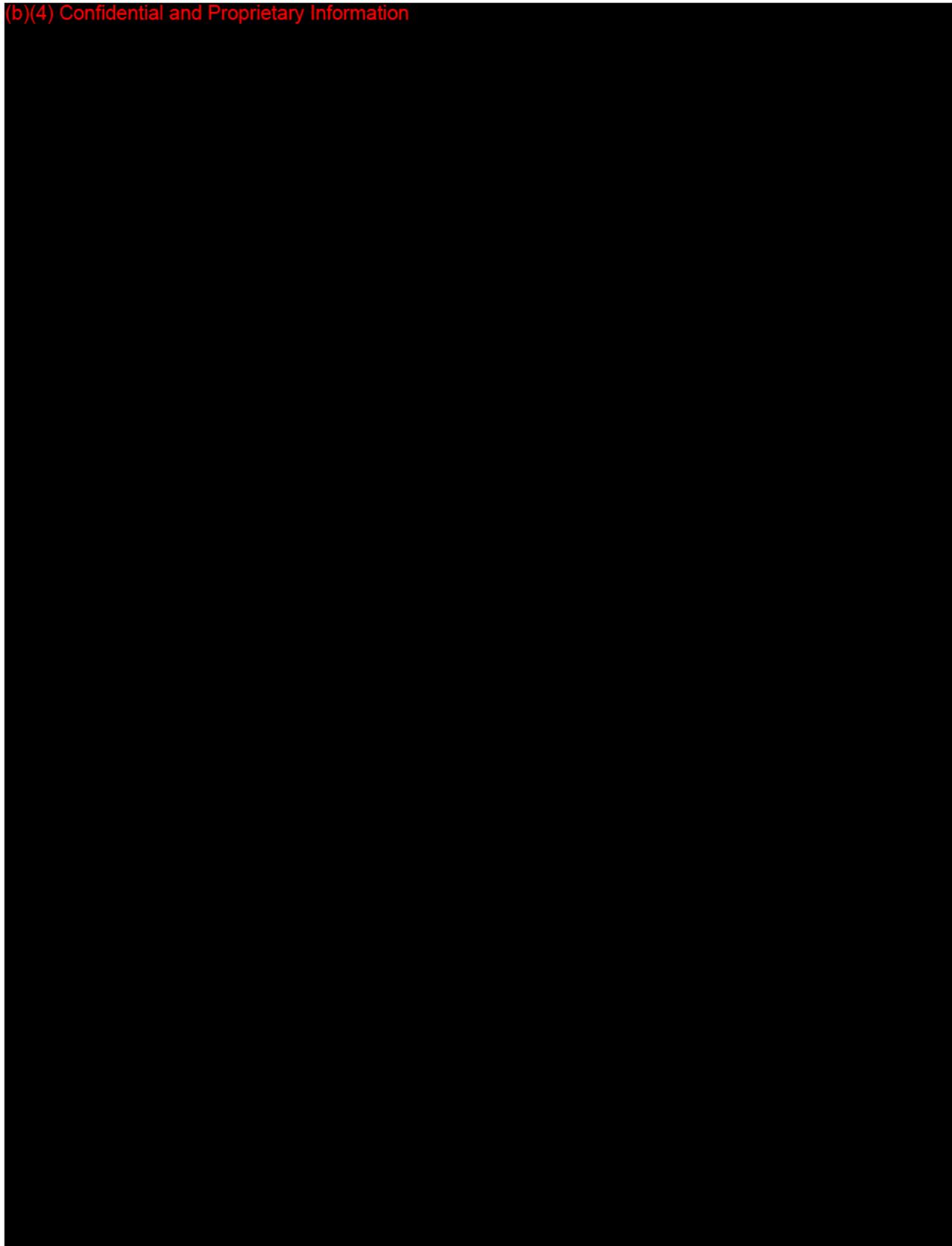
**Review Plan for Thermal Regulating System, 21 CFR 870.5900
(February 23, 2004)**

(b)(4) Confidential and Proprietary Information



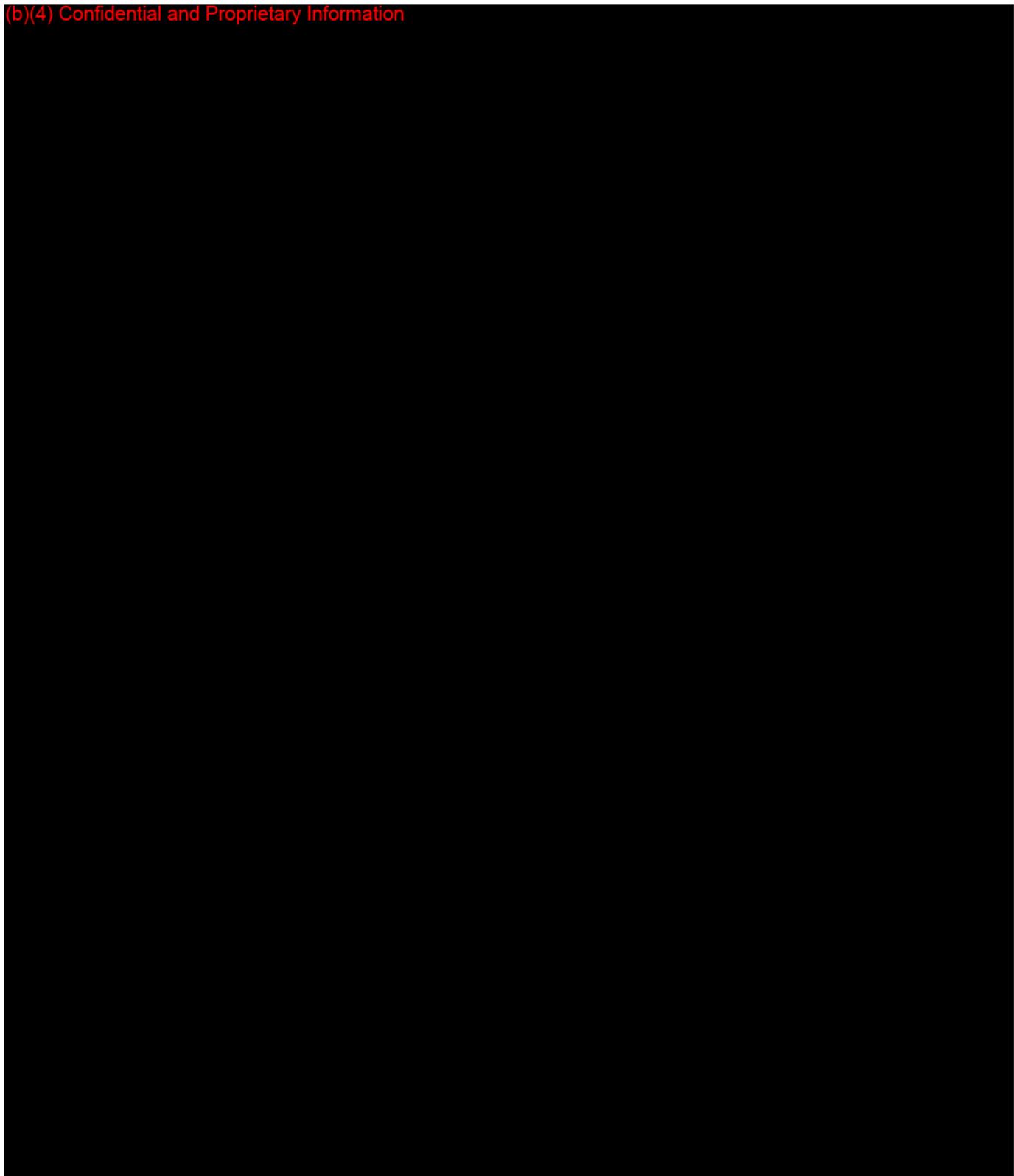
179

(b)(4) Confidential and Proprietary Information



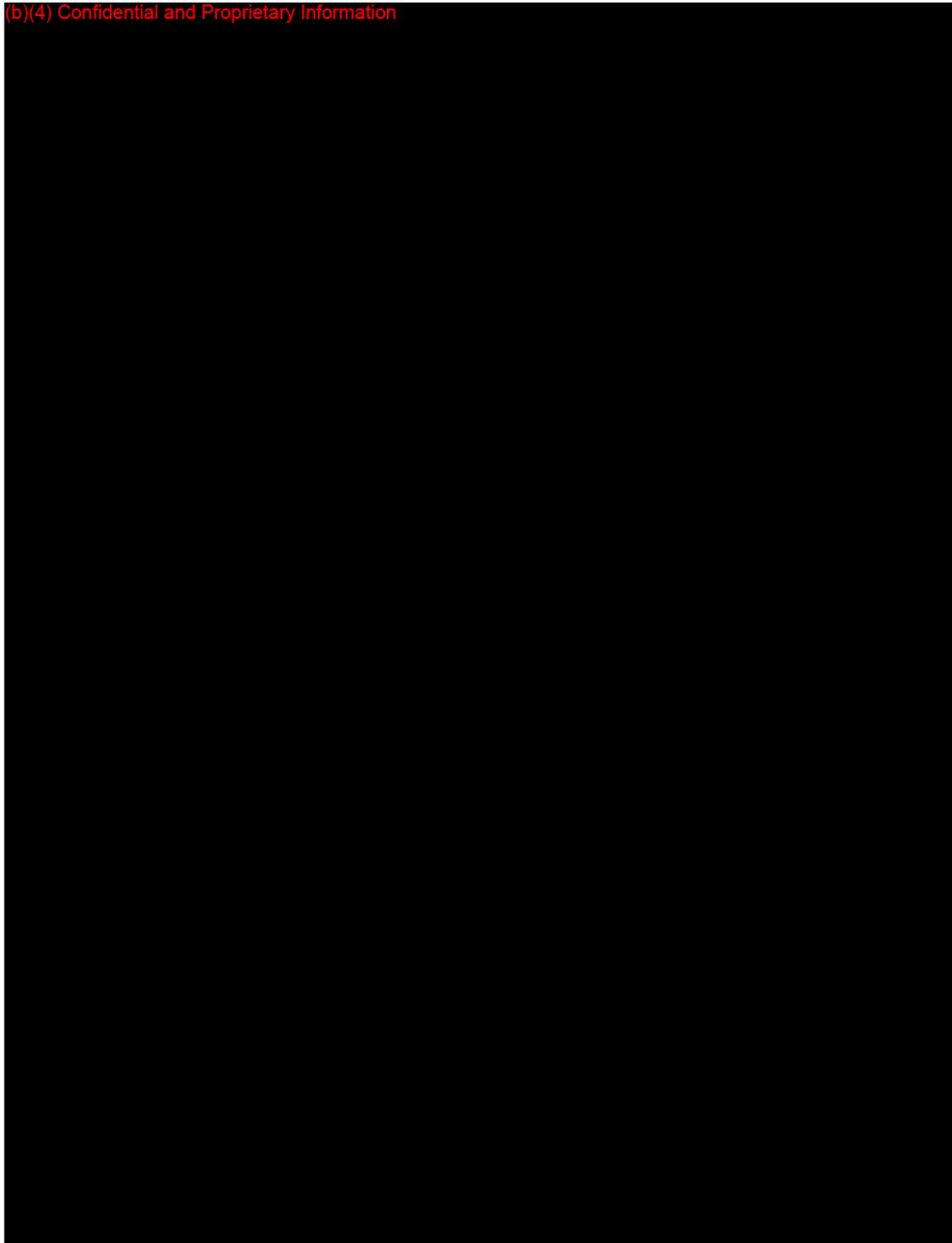
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(b)(4) Confidential and Proprietary Information



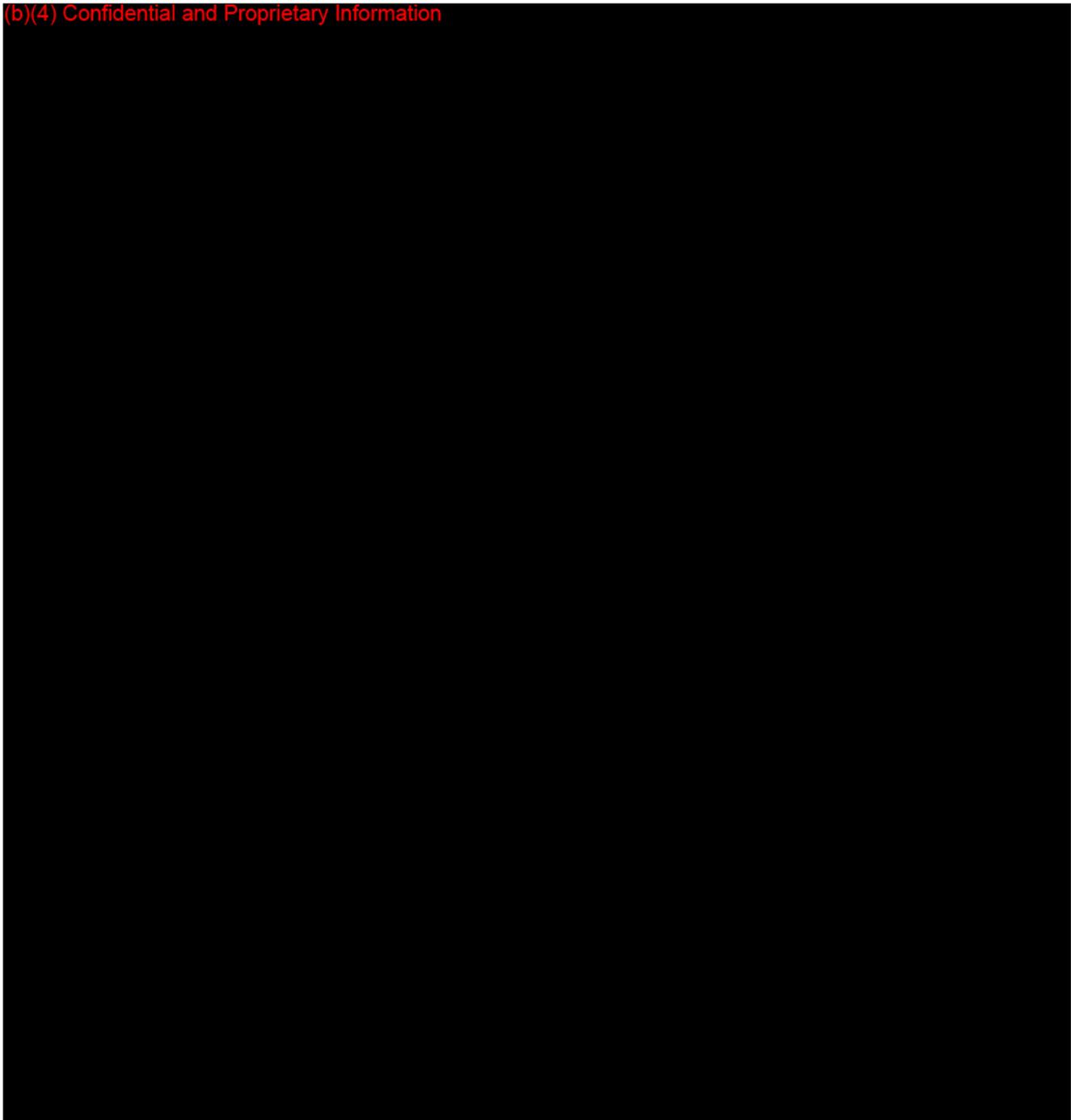
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(b)(4) Confidential and Proprietary Information



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(b)(4) Confidential and Proprietary Information



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**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.1 Summary of Safety and Effectiveness

2.2 Premarket Notification Truthful and Accurate Statement

2.3 Indication for Use

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**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.1 Summary of Safety and Effectiveness

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010**

**Non-Confidential Summary of Safety and Effectiveness
Page 1 of 3**

Dynatherm Medical, Inc.	Phone: (650) 777-4361
	Fax: (650) 777-4370
Official Contact:	Nathan Hamilton
Proprietary or Trade Name:	VitalHeat™
Common/Usual Name:	VitalHeat™
Classification Name:	VitalHeat
Predicate Device:	Aquarius Medical Corporation Thermo-STAT – K970367 Aquarius Medical Corporation AcroTherm – K003368

Device Description:

The Dynatherm Medical, Inc. VitalHeat™

- Warming Mitt
- Control Unit

The VitalHeat™ is a compact, thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand). The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand), which should not impede standard patient care and/o full body access.

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**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.1 Summary of Safety and Effectiveness

Indicated Used:

The VitalHeat™ designated to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to hand.

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
Non-Confidential Summary of Safety and Effectiveness
Page 2 of 3**

Patient Population:

The system is for use with patients experiencing cold who are 18 years of age and older.

Environments of Use:

The device is intended for use throughout healthcare facilities.

Contraindications:

The VitalHeat™ is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

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Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness
--

Page 3 of 3
510 (k) COMPARATIVE TABLE

COMPANY	DYNATHERM	AMC	AMC
PRODUCTS	VitalHeat™	ACROTHERM K003368	THERMO-STAT K970367
Intended use	Patient Temperature Control and Maintain	Patient Temperature Control and Maintain	Patient Temperature Control
Intended Environment of use	Healthcare Facilities	Healthcare Facilities	PACU
Contraindications	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease
Type	Sub Atmospheric Pressure/Water Paddle Disposable Mitt	Sub Atmospheric Pressure/Water Perfusion Pad in Camber	Negative Pressure/ Thermal Pad in Chamber
Pressure Device	Yes – Neg.	Yes – Neg.	Yes – Neg.
Sub-Atmospheric Pressure (mmHg)	40 ± 5 mmHg	40 ± 5 mmHg	40 – 60 mmHg
Electrical (AC)	Yes	Yes	No
Temperature Range	≤ 45 ° C	≤ 45 ° C	≤ 45 ° C
Application Site	Hand	Distal Limb	Distal Limb
Control System			
Control Type	Mirco - Logic	Mirco - Logic	N/A
Size	16 x 6 x 6 In.	14 x 6 x 5 In.	N/A
Weight	15.0 Lbs.	9.30 Lbs.	N/A
Mobility	Hand-Held IV Pole MTG Table Top	Hand-Held IV Pole MTG Table Top	N/A
Water Tank	200 ml	400 – 500 ml	N/A
Flow Rate	> 1000 ml/Min.	< 500 ml/Min.	N/A
Safety			
High Temperature Alarm	Yes	Yes	No
Water Level	Yes	Yes	N/A
Sub-Atmospheric Pressure	Yes LED and Audible	Yes LED and Audible	Yes LED Only

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Timer	Yes	No	No
Seal	No	Yes	N/A

**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.2 Premarket Notification Truthful and Accurate statement

I certify that, in my capacity as a President of Dynatherm Medical, Inc, I believe to the best of my knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material fact has been omitted.

Nathan Hamilton
President/CEO
Dynatherm Medical, Inc.

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**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.3 Indications for Use

510(k) Number: _____ (To be assigned)

Device Name: VitalHeat™

Intended Used: The VitalHeat™ is designed to non-invasively treat hypothermic patients by warming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

or

Over-the-Counter Use

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(Per CFR 801.109)

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**Premarket Notification 510(k)
Section 4 – Device Description**

VitalHeat™

- 4.0 Device Description**
- 4.1 Background and Modification of AcroTHERM**
- 4.2 Summary of Device Features**
- 4.3 Intended Use**
- 4.4 Patient Population**
- 4.5 Contraindications**
- 4.6 Environments of Use**
- 4.7 Power Specifications**
- 4.8 Maintenance**
- 4.9 Accessories**
- 4.10 Materials**
- 4.11 Testing and Risk Analysis**
- 4.12 Operating Temperatures**

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Premarket Notification 510(k)
Section 4 – Device Description

VitalHeat™

Person limits the transfer of heat from superficial surfaces, which can also prevent from the core temperature from increasing. Current methods used in healthcare facilities, such as forced-air rewarming, can be ineffective in overcoming the "vasoconstrictive blockade." The VitalHeat™ efficiently warms the body non-invasively from the inside out, including the vital organs that comprise the majority of the thermal core.

Hypothermia is defined as the condition of a temperature-regulating organism when core temperature is below the set rang specified for the normal active state of the species. Hypothermia has significant clinical consequences, including:

1. Increased risk of cardiac mortality and morbidity.
2. Increased infection rates.
3. Increased recovery time.
4. Increased fluid requirements.

Recovery from cold and decreased core temperature are dependent on an individual's ability to prevent further heat loss from the body core, while generating and/or maintaining as much heat/energy within the body core thermal compartment. When the core temperature falls below the desired set point, involuntary physiological responses occur to prevent further heat loss. Heat flux between the periphery (i.e., skin) and body core is a function of the amount of blood flowing between the core thermal compartment and the periphery (skin), especially the specialized heat transfer areas (palms of the hand, soles of the feet, cheeks, nose, and ears). The flow of blood to the skin is a function of peripheral vasomotor tone. When vasodilated, there is a free exchange of heat between the body core and the periphery. When vasoconstricted, this exchange of heat from the periphery to the body core is restricted.

A reduction in core temperature causes a vasoconstrictive response that is maintained until core temperature returns to the desired normothermic set point of the individual. This response is controlled, at a 4:1 ratio, by the body core temperature, versus the superficial (skin) temperature. Therefore, heating of the skin has only a limited effect on core temperature due to vasoconstrictive blockade resulting from the reduction in core temperature.

The VitalHeat™ approaches the rewarming dilemma by adding sub-atmospheric pressure combined with a thermal load applied to a specialized heat transfer area (hand). By mechanically distending the specialized heat exchange vessels, heat is transferred more efficiently to the body core.

The VitalHeat™ system comprises the following components:

1. Control unit with pre-connected Paddle
2. Disposable Warming Mitt.

Diagrams depicting the two main components and their subassemblies are in Attachment A.

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Design and performance criteria are found in **TAB #13**.

Premarket Notification 510(k)
Section 4 – Device Description

VitalHeat™

Sub Atmospheric Pressure Source:

A key ingredient of the technology is the ability to provide sub-atmospheric pressure in the localized area being treated. In a patient experiencing a reduction in core temperature, the VitalHeat™ acts to increase core body temperature and reduce the physical discomfort by the simultaneous application of heat and sub-atmospheric pressure to the treated area (hand). These areas are documented as primary heat exchangers that the body utilizes to respond to changes in core temperature. In a hypothermic patient, the application of heat alone to these same areas will not efficiently increase core body temperature due to the vasoconstrictive blockade of the blood vessels in the periphery.

The VitalHeat™ is designed to apply of 40 +/-5-mmHg sub-atmospheric pressure to the treated area. Treatment of a single appendage is sufficient to increase the heat transferred to the body core. This low level of sub-atmospheric pressure manually creates vasodilation in the treated appendage, thus allowing the thermal load applied to the skin to be more efficiently transferred to the blood stream and, ultimately, the body core.

The source of the sub-atmospheric pressure is a vacuum pump incorporated in the control unit.

Temperature Measurement:

In clinical tests performed with the Acrotherm cleared under K003368 thermocouple inserted into the ear was used to measure tympanic temperature. Tympanic temperature is considered to be an accepted measure of core body temperature. It is anticipated that routine methods (e.g., infrared thermometers used in the ear) will be the method used by most clinicians in assessing core body temperature. Because of the general availability of such devices, it is not anticipated that a body temperature-measuring device will be included with the VitalHeat™ system.

Safety Features

Controls to prevent overheating of the patient:

As the VitalHeat™ system rewarms cold patients, the thermoregulatory system of the body self-regulates to adapt vasomotor tone to changes in core temperature. As core temperature increases, the periphery circulatory system specializing in heat transfer increases the vasodilation, allowing for the effective elimination of excess heat. In the event the body is maximally vasodilated and heat is still applied, the patient will perspire to assist in the elimination of excess heat. Once core body temperature has been returned to an individual's set point, the body's own physiologic thermoregulatory system adapts to maintain that set point.

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A series of single logic controls work together to ensure that the system operates safely.

Premarket Notification 510(k)
Section 4 – Device Description

VitalHeat™

4.1 Background and Modification of AcroTherm

The benefit of warming devices in the clinical setting for managing a patient's temperature has been established. These benefits include increased healing response, decreased cardiac morbidity, increased patient comfort and reduced recovery time.

The Vital Heat™ temperature management device is a modification of the 510(K) device, the AcroTherm- K003368. The Vital Heat™'s technology for applying a sub-atmospheric pressure on a appendage and applying heat is the same as the Acrotherm

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**Premarket Notification 510(k)
Section 4 – Device Description**

VitalHeat™

Section #11 includes drawings of the VitalHeat™. Below is a summary of the device features

4.2 Summary of Device Features

Summary of Device Features

PRODUCT	VitalHeat™
Intended Use	Patient Temp. Management
Type	Negative Pressure/ Water Heated Aluminum Dome
Pressure Device	Yes-sub-atmospheric
Sub-atmospheric pressure (mmHg)	40±5
Electric (AC)	Yes
Temp. Range	43° + .3 - 1° C
Application Site	Distal Limb (hand)
Disposable Type	Single use Mitt
Control System	
Controller Type	Micro-logic/hardware
Size	14x6x5 in
Weight	15 lb
Mobility	Hand-held
Water Tank	300 – 350 ml
Safety	
High Temperature Alarm	Yes
Water Flow Alarm	Yes
Sub-Atmospheric Pressure Alarm	Yes
Electrical Safety	Yes UL 2601-1 and IEC 601-1-2

4.3 Intended Use

The VitalHeat™ is a compact and portable warming device for use in healthcare facilities to help

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recover patients from the discomfort and consequences of lowered body temperature. This device combines sub-atmospheric pressure and heat on one heat-exchanging extremity.

**Premarket Notification 510(k)
Section 4 – Device Description**

VitalHeat™

4.4 Patient Population

The system is for use with patients 18 years of age and older.

4.5 Contraindications

The VitalHeat™ is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

4.6 Environments of use

Health care facilities, including hospitals, ICUs, Ors, Ers, PACU, burn units and medical/surgical floors.

4.7 Power specifications

The heater and power supply are operated under 120V AC. The power supply provides 12V DC power to the pumps for vacuum and water.

4.8 Maintenance

The heat exchanger paddle does not require maintenance. Periodic inspection for the function of the latch should be made. Cleaning of the paddle and is performed when needed with a mild hypoallergenic soap and water. A mild, non-toxic disinfectant spray can also be used.

The control unit and tubing set should be periodically inspected for damage. See **Tab # 10** for User's Manual Instructions.

4.9 Accessories

- Wall Mount

Drawings of the accessory have been included in **Tab # 12**.

4.10 Materials

See **Tab #6**, Biocompatibility, for a table of materials.

**Premarket Notification 510(k)
Section 4 – Device Description**

VitalHeat™

4.11 Testing and Risk Analysis

Testing of the device has been composed of two groups of tests: Functional and Safety.

Functional/bench testing:

We have performed several functional bench tests.

The Design Criteria and Test Report are located behind **Tab #13**.

Safety Testing:

Beside the safety testing also includes our bench testing. Electrical safety and EMC (electromagnetic compatibility) testing performed by Underwriters Laboratories (UL). Compliance to UL2601-1, and 601-1-2 will be certified.

Mechanical safety will be determined through testing from UL in combination with in-house testing and external packaging tests according to ISTA Procedure 2A.

Risk Analysis was completed. This report is located behind **Tab # 14**.

4.12 Operating Temperature

The materials utilized in the warming mitt, tubing set, control unit, and disposables can be used within the following environmental temperature range: 5°C to 50°C.

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Joseph P. Murnane Jr. To: Morten S. Christensen/SCL/ULI@ULI
02/23/2004 09:54 AM cc:
Subject: Re: Review plan for 870.5900 []

Hello Morten,

The plan can be sent in for FDA review. Sorry I couldn't get back to you Friday.

Rgds,

Joseph Murnane
Principal Engineer (PDE)
Medical
UL Inc.- Melville, NY
P: 631 271 6200
F: 631 439 6231

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Morten S. Christensen

Morten S. Christensen To: Joseph P. Murnane Jr./MEL/ULI@ULI
02/20/2004 05:13 PM cc:
Subject: Re: Review plan for 870.5900 []

Hi Joe,

I will forward the review plan to the FDA Monday morning. Pls. reply if you have comments to the review plan.

Thanks.

MORTEN SIMON CHRISTENSEN
Staff Engineer & FDA Office Coordinator
Medical Devices Conformity Assessment Services

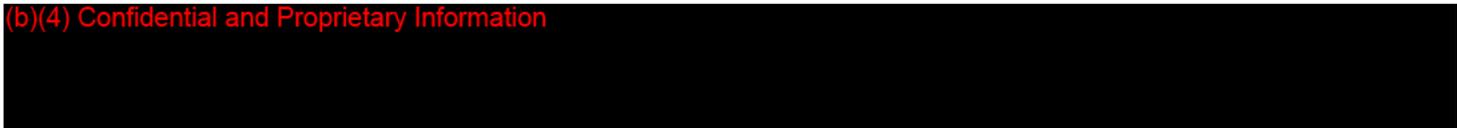
Ph: (408) 876-2016
Fx: (408) 556-6218

Please click <http://www.ul.com/medical> for information about our services
Morten S. Christensen

Morten S. Christensen To: Joseph P. Murnane Jr./MEL/ULI
02/18/2004 09:18 AM cc:
Subject: Review plan for 870.5900

Hi Joe,

(b)(4) Confidential and Proprietary Information



late.



Review Plan.doc

Product description.



SECTION 2.0 PREMARKET 510(K).c

I would like to get the review plan to the FDA by Friday morning.

Thanks.

Morten

MORTEN SIMON CHRISTENSEN
Staff Engineer & FDA Office Coordinator
Medical Devices Conformity Assessment Services

Ph: (408) 876-2016

Fx: (408) 556-6218

Please click <http://www.ul.com/medical> for information about our services

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DYNATHERM MEDICAL, INC.

510 (K) PREMARKET NOTIFICATION

VitalHeat™ - a modification of:

- **AcroTHERM, Cleared under K003368**

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
Phone: (650) 777-4361
Fax: (650) 777-4370
E-Mail: john.dynathermmedical.com**

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Dynatherm

February 12, 2004

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

RE: 510(k) Premarket Notification – Modification to K003368
Dynatherm Medical Inc. - VitalHeat™

ATTN: Document Control Clerk

This submission is a significant modification of a previously approved device. Aquarius Medical Corporation received an SE letter under K003368 cleared December 1997 for a Product called AcroTherm™.

We are filing this modification desiring to introduce a new design, technology materials, and manufacturing for this thermal regulation device.

The following Premarket Notification 510(k) submission has been prepared in accordance with the Draft Guidance for Format and Content for Premarket Notification 510(k).

For your convenience we have included the Premarket Notification Submission Cover Sheet. Also As requested, the 510(k) Safety and Effectiveness Summary and the Truthful and Accurate Statement have been placed on separate pages.

We have prepared the **Indication for use** on a separate sheet. It is located in Section #2 – Certification and Summaries.

The official correspondent for this submission is Mr. John Kane (Senior Engineer) of Dynatherm Medical, Inc.

Sincerely,



Nathan Hamilton
President, CEO
Dynatherm Medical, Inc.

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CDRH SUBMISSION COVER SHEET				
Date of Submission: February 12, 2004			FDA Document Number:	
Section A Type of Submission				
PMA	PMA Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original submission <input type="checkbox"/> Modules submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review	<input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<input checked="" type="checkbox"/> Original submission <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Additional information <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	<input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify)
IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Describe submission:
Section B Applicant or Sponsor				
Company / Institution name: DYNATHERM MEDICAL, INC.		Establishment registration number:		
Division name (if applicable):		Phone number (include area code): (650) 777-4361		
Street address: 819 MITTEN RD, SUITE 42		FAX number (include area code): (650) 777-4370		
City: Burlingame	State / Province: CALIFORNIA	Country: USA	ZIP / Postal Code: 94010	
Contact name: NATHAN HAMILTON				
Contact title: PRESIDENT		Contact e-mail address: Nathan@dynathermmedical.com		
Section C Submission correspondent (if different from above)				
Company / Institution name: DYNATHERM MEDICAL, INC.		Establishment registration number:		
Division name (if applicable):		Phone number (include area code): (650) 777-3461		
Street address: 819 MITTEN RD, SUITE 42		FAX number (include area code): (650) 777-4370		
City: Burlingame	State / Province: CALIFORNIA	Country: USA	ZIP / Postal Code: 94010	
Contact name: JOHN R. KANE				
Contact title: PROJECT ENGINEER		Contact e-mail address: john@dynathermmedical.com		

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		FDA Document Number:
Section D1 Reason for Submission - PMA, PDP, or HDE		
<input type="checkbox"/> New device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement <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"/> Response to FDA correspondence: <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site Other reason (specify):	<input type="checkbox"/> Change design, component or specifications: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Labeling Change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <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"/> Distributor <input type="checkbox"/> Report submissions: <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"/> Change in ownership <input type="checkbox"/> Change in correspondent
Section D2 Reason for Submission - IDE		
<input type="checkbox"/> New device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion / extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <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"/> Continuing availability request <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <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"/> Report Submission: <input type="checkbox"/> Current investigator <input type="checkbox"/> Annual progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approval <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
Section D3 Reason for Submission - 510(k)		
<input type="checkbox"/> New device <input type="checkbox"/> Addition or expanded indications <input checked="" type="checkbox"/> Other reasons (specify):	<input checked="" type="checkbox"/> Change in technology <input checked="" type="checkbox"/> Change in design	<input checked="" type="checkbox"/> Change in materials <input checked="" type="checkbox"/> Change in manufacturing process

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				FDA Document Number:	
Section E Additional Information on 510(k) Submission					
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data:	
1 DWJ	2	3	4	<input checked="" type="checkbox"/> 510(k) Summary attached	
5	6	7	8	<input type="checkbox"/> 510(k) Statement	
Information on devices to which substantial equivalence is claimed:					
510(k) Number		Trade or Proprietary or Model Name		Manufacturer	
1 K003368		1 ACROTERM		1 AQUARIUS MEDICAL CORPORATION	
2 K970367		2 Thermo-STAT		2 AQUARIUS MEDICAL COPORATION	
Section F Product Information - Applicable to ALL Applications					
Common or usual or classification name: THERMAL REGULATING SYSTEM					
Trade or Proprietary or Model Name				Model Number	
1 VitalHeat™				VH - 1020	
2					
3					
4					
FDA document numbers of all prior related submissions (regardless of outcome): N/A					
1 K970367	2 K003368	3	4	5	6
Data included in submission: <input checked="" type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal trials <input type="checkbox"/> Human trials					
Section G Product Classification - Applicable to ALL Applications					
Product code: DWJ		C.F.R. section: 21 CFR 870.5900		Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Classification panel: CARDIOVASCULAR					
Indications (From labeling): The VitalHeat™ is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.					

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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:	
Section H Manufacturing / Packaging / Sterilization Sites			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number:	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name: DYNATHERM MEDICAL, INC.		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): (650) 777-4361	
Street address: 819 MITTEN ROAD, SUITE 42		FAX number (include area code): (650) 777-4370	
City: BURLINGAME	State / Province: CALIFORNIA	Country: USA	ZIP / Postal Code: 94010
Contact name: NATHAN HAMILTON			
Contact title: PRESIDENT		Contact e-mail address: nathan@dynatherm medical.com	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:		Contact e-mail address:	

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**Premarket Notification 510(k)
Section 1 – General Information**

VitalHeat™

1.0 General Information

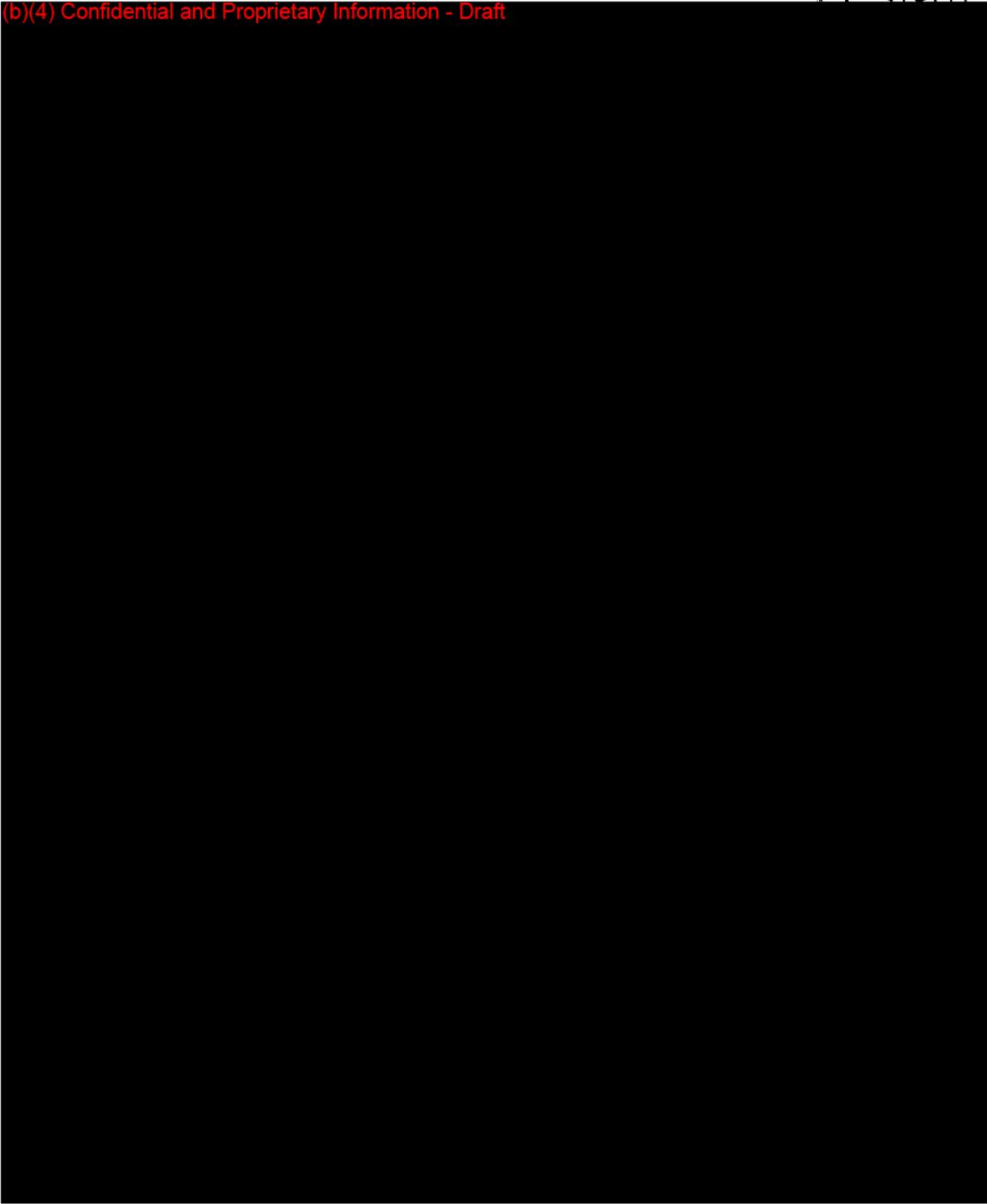
- 1.1 Establishment Name: Dynatherm Medical Corporation
819 Mitten Road
Suite 42
Burlingame, CA 94010
- 1.2 Establishment Number:
- 1.3 Official Correspondent: John R. Kane
- 1.4 Device Name: VitalHeat™
- 1.5 Classification: Class II
- 1.6 Classification Reference: 21 CFR 870.5900
- 1.7 FDA Classification Code: DWJ
- 1.8 Classification Panel: Cardiovascular Panel
- 1.9 Classification Name: Thermal Regulating System
- 1.10 Reason for Submission: Modification to a device cleared under
K003368
- 1.11 Predicate Devices: Aquarius Medical Corporation, Inc.
Thermo-STAT – K970367
Cleared December 17, 1997
- Aquarius Medical Corporation
Acro Therm – K003368
Cleared January 19, 2001
- 1.12 Performance Standards: None applicable under Section 514
- 1.13 Intended Use: The VitalHeat™ is designed to Non-Invasively
treat hypothermic patients by warming their body core.
This accomplished with local application of negative
pressure and thermal load (heat) to a distal appendage

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**Premarket Notification 510(k)
Section 1 – General Information**

VitalHeat™

(b)(4) Confidential and Proprietary Information - Draft



03 31-04

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**Premarket Notification 510(k)
Section 1 – General Information**

VitalHeat™

-
- | | | |
|------|----------------------|--|
| 1.14 | Intended Population: | For use in patients requiring external thermal management. |
| 1.15 | Contraindications: | Patients under the age of 18 and with peripheral vascular disease. |
| 1.16 | Environments of Use: | Health Care Facilities. |

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Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
Non-Confidential Summary of Safety and Effectiveness
Page 1 of 3**

Dynatherm Medical, Inc.	Phone: (650) 777-4361
	Fax: (650) 777-4370
Official Contact:	Nathan Hamilton
Proprietary or Trade Name:	VitalHeat™
Common/Usual Name:	VitalHeat™
Classification Name:	Thermal Regulating System
Predicate Device:	Aquarius Medical Corporation Thermo-STAT – K970367 Aquarius Medical Corporation AcroTherm – K003368

Device Description:

The Dynatherm Medical, Inc. VitalHeat™

- Warming Mitt
- Control Unit

The VitalHeat™ is a compact, thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand). The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand), which should not impede standard patient care and/o full body access.

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**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.1 Summary of Safety and Effectiveness

Indicated Used:

The VitalHeat™ designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to hand.

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
Non-Confidential Summary of Safety and Effectiveness
Page 2 of 3**

Patient Population:

The system is for use with patients experiencing cold who are 18 years of age and older.

Environments of Use:

The device is intended for use throughout healthcare facilities.

Contraindications:

The VitalHeat™ is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

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Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

Page 3 of 3
510 (k) COMPARATIVE TABLE

COMPANY	DYNATHERM	AMC	AMC
PRODUCTS	VitalHeat™	ACROTHERM K003368	THERMO-STAT K970367
Intended use	Patient Temperature Control and Maintain	Patient Temperature Control and Maintain	Patient Temperature Control
Intended Environment of use	Healthcare Facilities	Healthcare Facilities	PACU
Contraindications	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease
Type	Sub Atmospheric Pressure/Water Paddle Disposable Mitt	Sub Atmospheric Pressure/Water Perfusion Pad in Camber	Negative Pressure/ Thermal Pad in Chamber
Pressure Device	Yes – Neg.	Yes – Neg.	Yes – Neg.
Sub-Atmospheric Pressure (mmHg)	40 ± 5 mmHg	40 ± 5 mmHg	40 – 60 mmHg
Electrical (AC)	Yes	Yes	No
Temperature Range	≤ 45 ° C	≤ 45 ° C	≤ 45 ° C
Application Site	Hand	Distal Limb	Distal Limb
Control System			
Control Type	Micro - Logic	Micro - Logic	N/A
Size - Controller	16 x 6 x 6 In.	14 x 6 x 5 In.	N/A
Weight	15.0 Lbs.	9.30 Lbs.	N/A
Mobility	Hand-Held IV Pole MTG Table Top	Hand-Held IV Pole MTG Table Top	N/A
Water Tank	200 ml	400 – 500 ml	N/A
Flow Rate	> 1000 ml/Min.	< 500 ml/Min.	N/A
Safety			
High Temperature Alarm	Yes	Yes	No
Water Level	Yes – Water Flow	Yes	N/A
Sub-Atmospheric Pressure	Yes LED and Audible	Yes LED and Audible	Yes LED Only
Timer	Yes	No	No
Seal	Yes	Yes	N/A

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**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

03-31-04

[Handwritten signature]

2.1 Summary of Safety and Effectiveness

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010**

**Non-Confidential Summary of Safety and Effectiveness
Page 1 of 3**

Dynatherm Medical, Inc.

Phone: (650) 777-4361

Fax: (650) 777-4370

Official Contact:

Nathan Hamilton

Proprietary or Trade Name:

VitalHeat™

Common/Usual Name:

VitalHeat™

Classification Name:

VitalHeat

Predicate Device:

Aquarius Medical Corporation

Thermo-STAT – K970367

Aquarius Medical Corporation

AcroTherm – K003368

Device Description:

The Dynatherm Medical, Inc. VitalHeat™

- Warming Mitt
- Control Unit

The VitalHeat™ is a compact, thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand). The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand), which should not impede standard patient care and/o full body access.

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**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.1 Summary of Safety and Effectiveness

Indicated Used:

The VitalHeat™ designated to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to hand.

03-31-04
A. A. C. A. -

**Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010**

**Non-Confidential Summary of Safety and Effectiveness
Page 2 of 3**

Patient Population:

The system is for use with patients experiencing cold who are 18 years of age and older.

Environments of Use:

The device is intended for use throughout healthcare facilities.

Contraindications:

The VitalHeat™ is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

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Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

Page 3 of 3
510 (k) COMPARATIVE TABLE

03-31-04
Ab Ch

COMPANY	DYNATHERM	AMC	AMC
PRODUCTS	VitalHeat™	ACROTHERM K003368	THERMO-STAT K970367
Intended use	Patient Temperature Control and Maintain	Patient Temperature Control and Maintain	Patient Temperature Control
Intended Environment of use	Healthcare Facilities	Healthcare Facilities	PACU
Contraindications	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease
Type	Sub Atmospheric Pressure/Water Paddle Disposable Mitt	Sub Atmospheric Pressure/Water Perfusion Pad in Camber	Negative Pressure/ Thermal Pad in Chamber
Pressure Device	Yes – Neg.	Yes – Neg.	Yes – Neg.
Sub-Atmospheric Pressure (mmHg)	40 ± 5 mmHg	40 ± 5 mmHg	40 – 60 mmHg
Electrical (AC)	Yes	Yes	No
Temperature Range	≤ 45 ° C	≤ 45 ° C	≤ 45 ° C
Application Site	Hand	Distal Limb	Distal Limb
Control System			
Control Type	Mirco - Logic	Mirco - Logic	N/A
Size	16 x 6 x 6 In.	14 x 6 x 5 In.	N/A
Weight	15.0 Lbs.	9.30 Lbs.	N/A
Mobility	Hand-Held IV Pole MTG Table Top	Hand-Held IV Pole MTG Table Top	N/A
Water Tank	200 ml	400 – 500 ml	N/A
Flow Rate	> 1000 ml/Min.	< 500 ml/Min.	N/A
Safety			
High Temperature Alarm	Yes	Yes	No
Water Level	Yes	Yes	N/A
Sub-Atmospheric Pressure	Yes LED and Audible	Yes LED and Audible	Yes LED Only
Timer	Yes	No	No
Seal	No	Yes	N/A

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**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.2 Premarket Notification Truthful and Accurate statement

I certify that, in my capacity as a President of Dynatherm Medical, Inc, I believe to the best of my knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material fact has been omitted.



Nathan Hamilton
President/CEO
Dynatherm Medical, Inc.

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Indications for Use

510(k) Number (if known):

Device Name: VitalHeat™

Indications For Use:

The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by warming their body core. This accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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 _____

**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

03-51-04

[Handwritten signature]

2.3 Indications for Use

510(k) Number: _____ (To be assigned)

Device Name: VitalHeat™

Intended Used: The VitalHeat™ is designed to non-invasively treat hypothermic patients by warming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

or

Over-the-Counter Use

(Per CFR 801.109)

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**Premarket Notification 510(k)
Section 3 – Labeling**

VitalHeat™

3.0 Labeling

3.1 Labeling Content

3.2 Literature and Advertising

3.3 Other Information

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**Premarket Notification 510(k)
Section 3 – Labeling**

VitalHeat™

3.1 Labeling Content

See **Tab #10** For the Operator's Manual.

See **Tab #11** For Device Specific Labeling.

3.2 Literature and Advertising

Web Site: www.dynathermmedical.com

Hand Outs: See Enclosures

3.3 Other Information

The product is supplied non-sterile

uu



About

Applications

Benefits

News

Contact

Q & A

Technology

Dynatherm's innovative technology is based on the fundamental understanding of mammalian temperature regulation as described by Dr. Dennis Grahn of Stanford University Department of Biological Sciences. Dr. Grahn is the primary inventor of the technology licensed exclusively to Dynatherm.

Mammals are equipped with a sophisticated system for controlling core temperature. This is achieved through the means of specialized vascular structures located in the hairless areas of the body, primarily the palms of the hands and soles of the feet. These areas of the human body possess two separate and distinct vascular beds; one of nutrient blood flow, the other is a high volume vascular bed specifically for bringing large quantities of blood near the surface of the skin.

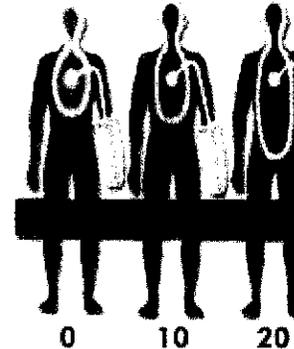
This second vascular bed is utilized by the body to shunt large quantities of blood to the skin when the body is overheated. When triggered by a drop in core temperature, these vascular beds constrict thus shunting blood back to the core. Hypothermic individuals have minimal blood flow to the skin and especially to the areas of the hands and feet. A common complaint of cold patients is one of hands or feet being cold. Blood flow into the extremity drops as much as 90% from the fully dilated state.

The body makes efficient use of the blood supply to control the core temperature. Heat is efficiently moved about the body by the blood supply. The skin and fat that overlay the body acts as an effective layer of insulation. This layer of insulation maintains the core temperature when the person is confronted by excessive heat or cold. When the blood supply to the skin is reduced as in cases of hypothermia, external sources of heat are poorly conducted through the skin and fat in an attempt to warm the core.

When a person becomes hypothermic from any cause, it is the vital organs that need to be warmed to counter the clinical consequences of the hypothermic state. Warming of skin and fat does little to improve mental status, reverse coagulopathy and decrease oxygen consumption. It is therefore imperative to get heat quickly to the core when treating a patient suffering from hypothermia.

Conventional methods of warming are slow and generally ineffective. These methods typically involve warm fluid, air or cloth blankets. Invasive techniques are significantly more efficient but are limited to application by a physician skilled in major vessel cannulation and pose many serious risks. There is currently no rapid, safe and effective technology on the market today that can be used to recover a patient from temperature disorders.

In cases of hyperthermia the ability of the individual to remove excess heat from the body has been exceeded. In order to prevent heat stroke the individual to rapidly remove heat from the core. This process can be made more efficient by maximally dilating these small vascular structures in the hands and feet. With these vascular structures maximally dilated, a cool medium is placed against the hand or foot and heat is transferred at an increase rate out of the body. This treatment may be combined with other forms of therapy such as fluid resuscitation for increased effectiveness.



The patented Dynatherm technology nor blood instead of warming superficial skin patients warm up faster and the clinical consequences of hypothermia are significantly reduced. TI time can be cut from hours to minutes. The technology also allows for full patient assessment and treatment easier. The w covers one hand or one foot.

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Applications

In clinical practice there is often the need to maintain or rapidly restore normothermia in a hypo or hyperthermic patient. Many situations require rapid intervention as in the case of emergency care or surgery. The ability to restore a patient's temperature can significantly impact overall mortality and morbidity. Examples in which cooling or warming therapy would be indicated are:



Hypothermia secondary to:

- Surgical procedures with use of general anesthesia
- Emergency trauma
- Sepsis
- Overdose
- Head injury
- Stroke
- Brain cancer
- Diabetes
- Environmental exposure
- Therapeutic hypothermia

Hyperthermia secondary to:

- Infection
- Malignant hyperthermia
- Exertional hyperthermia
- Environmental hyperthermia
- Head injury
- Stroke

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Benefits

Speed. The DynaTherm technology cuts patient warming and cooling from hours to minutes. This translates into savings for the healthcare provider and the patient.

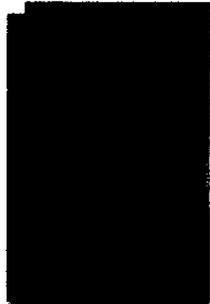
Patient access. Patients no longer need to be covered with a warming mattress, sheet or blanket. This provides for immediate patient access for assessment, diagnostic tests and treatment.

Multipurpose. The DynaTherm technology can warm or cool patients.

Small. The DynaTherm technology doesn't require a cart or stand of its own. No bigger than a portable vital sign monitor, the DynaTherm technology goes anywhere the patient goes and doesn't get in the way.

Smart. The DynaTherm technology knows when a patient is normothermic and stops the warming process. DynaTherm's smart controller makes patient safety a priority.

Easy to use. Designed and built with the guidance of working healthcare professionals, the DynaTherm technology is easy to apply and operate. This customer driven design minimizes training time and cost and maximizes the benefits of the technology.



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Visit us at AORN in San Diego. March 23, 24, 25. Booth 4228.



<http://www.dynathermmedical.com/news.html>

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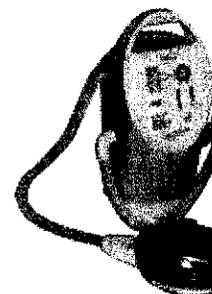
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Questions about our site: webmaster@dynathermmmedical.com



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Company Background

Dynatherm Medical, Inc. was founded in 2002 as part of a technology and product "spin out" from Kobayashi, a Japanese pharmaceutical company. Dynatherm acquired FDA approved products for core body temperature management as well as key assets including five issued patents and numerous pending patents.

Dynatherm's technology takes advantage of the body's natural thermoregulatory system to channel thermal energy non-invasively to the body's core six times more quickly than other non-invasive methods. Dr. Dennis Grahn invented the technology at Stanford University, and Dynatherm is the exclusive licensee of this core technology.

Dynatherm is commercializing this technology for core body temperature management. Dynatherm's first product is configured as a disposable for recovery from and prevention of hypothermia in surgical procedures, emergency rooms, and for field applications. Hypothermia is associated with increased surgical complications and morbidity, prolonged recovery from anesthesia, and longer hospital stays. Follow on products include cooling applications. Dynatherm's technology improves patient outcomes while decreasing healthcare costs.



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Management Team

Dr. Timothy Mills, Chairman

With nearly twenty years of experience in biomedical research and corporate management, Dr. Timothy Mills joined Sanderling as an Operating Partner in July 1998, and was promoted to Managing Director in 2000.

At Sanderling, Dr. Mills has focused on early stage investments in medical devices, biotherapeutics, and i-Health. He serves Sanderling portfolio companies as director, chief executive officer or management team member.

Prior to joining Sanderling, Dr. Mills served as the Corporate Vice President of New Business Development and Chief Scientific Officer of Target Therapeutics, a medical device company that was acquired by Boston Scientific for \$1.2 billion in 1997. He also served as the Director for Prograft Medical, a Target affiliate.

Prior to joining Target in 1994, Dr. Mills served as Director of Business Development and Advanced Research and Development in the Interventional Cardiology Division of Baxter Healthcare. Dr. Mills' academic appointments include service as the Director of the Artificial Heart Program at the University of California, Irvine Medical Center and membership in the University of California, San Francisco Radiology Department.

Dr. Mills received his Ph.D. in Bioengineering from the University of California, Berkeley and San Francisco School of Medicine, his M.S. in Electrical Engineering and Computer Science from the University of California, Berkeley, and his B.S. in Electrical Engineering from the University of Colorado, Boulder.

Nathan Hamilton, President and CEO

Nathan Hamilton is a founder and Managing Director of Archangel BioVentures, LLC, which specializes in entrepreneurial biomedical investments. Mr. Hamilton has played an active management or advisory role in several biomedical startups and buyouts including Biolog, Dynatherm Medical, Juvenon, Metragen, Micro Fluidic Systems, and Operon Technologies. As President of Operon, he built the business into the number one synthetic DNA supplier worldwide and executed a sale to QIAGEN. He currently serves on the board of five companies.

Mr. Hamilton received his B.A. in Physics from the University of California, Berkeley and his Masters of Business Administration from Harvard University Graduate School of Business.

Lawson Fisher, Vice President of Engineering

Lawson Fisher brings over 20 years of engineering and project management experience to Dynatherm. Areas of expertise include biotechnology, scientific instruments, and robotic production equipment for high volume manufacturing.

Prior to joining Dynatherm, Mr. Fisher developed genomic and proteomic instruments for Hewlett Packard, Protogene, and Zyomyx. At HP he spent six years designing high volume production equipment for several HP divisions.

Mr. Fisher received his B.S. in Electrical Engineering and a M.S. in Mechanical Engineering from Stanford University.

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Investors

Sanderling

Founded in 1979, Sanderling is among the oldest investment firms dedicated to building new biomedical companies. Sanderling's investment philosophy is that significant companies are best built in close working partnerships with entrepreneurs.

Sanderling's unique approach combines a specialized investment focus with active management and long-term commitment to ensure the highest rates-of-return for both its entrepreneurs and investors.

Biomedical investing has been a viable sector in the technology markets for more than thirty years, and in the past ten years has experienced accelerated growth. Since its inception, Sanderling has supported over 40 biomedical companies from very early stages through commercial development, earning consistently high rates-of-return on its venture investments.

Sanderling emphasizes early-stage financing and active management of its portfolio companies. Sanderling and its principals play an active role in new ventures by providing seed and early-stage funding, contributing management leadership and administrative support, developing cost-control strategies to extend available dollars, supplying technical and regulatory expertise where needed, and offering the insight and perspective of those who have "done it before." The partnership has sufficient capital to support the companies in later-stage financing, protecting its investments from excessive dilution.

As in any long-term investment vehicle, identifying ventures with strong potential and nurturing them today sows the seeds for tomorrow's harvest. Following its own best instincts, talents, and strategy, Sanderling continues to bring significant new technologies to market, and achieve successful outcomes for both its portfolio and investors.

Archangel BioVentures, LLC

Archangel BioVentures was founded in 2001 and specializes in entrepreneurial biomedical investments. Archangel fills the gap between typical angel and venture capital investment amounts, and Archangel leverages its investment dollars by providing active management and advisory services to portfolio companies. Archangel typically invests in biomedical companies with existing products, proprietary technology, issued patents and existing or near term revenue opportunities where a modest amount of capital can quickly accelerate the business.

FOIA Request #2016-6393; Released by CDRH on 09-12-2016

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No openings at this time

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Hypothermia Treatment

Dynatherm
MEDICAL, INC.

Introducing The New Standard In Patient Rewarming

Hypothermia complicates overall patient care and negatively impacts mortality and morbidity. Rapid, effective warming of a patient can quite literally save their life. Hypothermia impedes clotting mechanisms, increases oxygen consumption, increases cardiac irritability and is just plain uncomfortable.

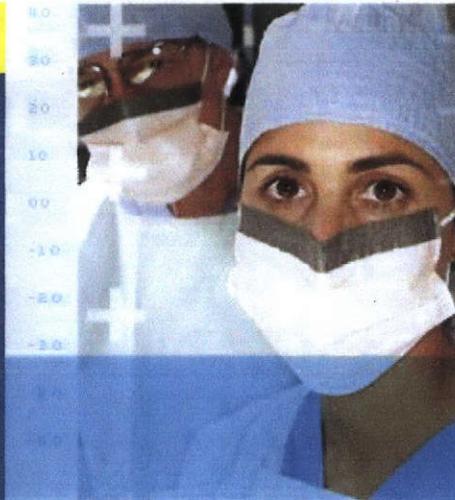
Rapid return to normothermia not only improves patient outcomes, it will improve your hospital departments bottom-line. Quicker thermal recovery translates into less medications, less blood products and less staff-time attempting to warm the patient.

Vitalheat is a revolutionary technology invented at Stanford University. Adapted from NASA, **Vitalheat** combines heat and vacuum to rapidly warm a patient. Non-invasive and simple to use, **Vitalheat** can shave hours off typically rewarming times seen with surface warming methods.

Vitalheat utilizes low-level vacuum to mechanically vasodilate vascular beds in the hand, resulting in a substantial increase in extremity blood flow. As the blood passes by the surface of the hand, heat is transferred from the device to the blood. The warmed blood is returned to the central circulation and rapidly warms the body core.

Effective for ER, ICU, PACU, OR or anywhere patient rewarming is needed.

Don't hesitate to learn more about how you can improve patient care while reducing costs, call today.



Vitalheattm

Temperature Management System

- Rapid Core Rewarming
- Maximizes Body Accessibility
- Non-invasive
- Compact Design

PRINCIPLE OF ACTION:
Rapid heat transport via bloodstream
to heart and vital organs

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Introducing The New Standard for Treating Hypothermia

When there are only minutes between life and death, emergency and hospital care professionals have to react quickly, and often the thermal condition of the patient is a secondary consideration. Our new technology, the Vitalheat™, provides a means of eliminating hypothermia as a confounding variable in the treatment of a trauma victim. Vitalheat is designed to rapidly rewarm the hypothermic patient. Vitalheat's compact size allows for maximum body accessibility (applied to the hand) and its portability enables performance during mobile transport. Nobody should suffer from hypothermia after they have been rescued and treatment has been started.

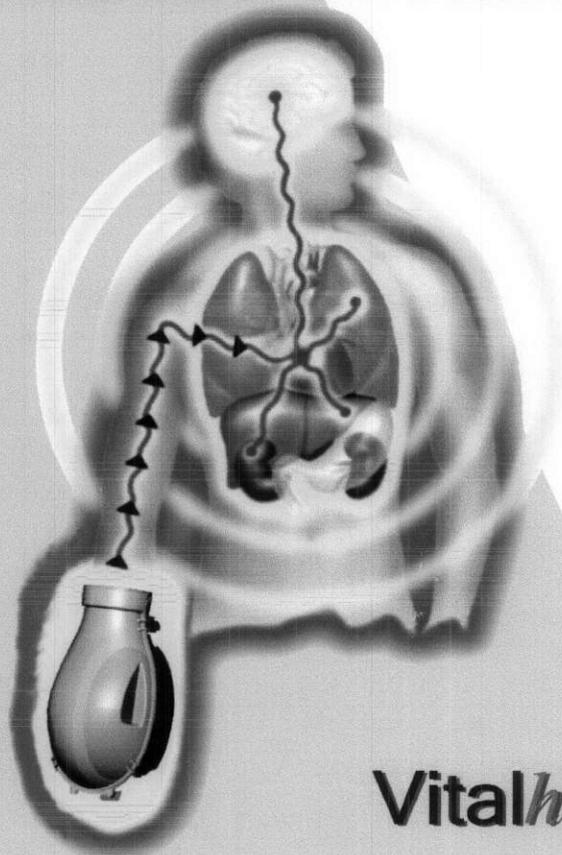
Getting Heat to the Core Quickly

The thermal core of a human is comprised of the internal organs that function optimally in a narrow temperature range. The organs that make up the thermal core represent only a small portion of the total body mass (less than 10%). Hypothermia is the condition when the temperature of the thermal core falls below the functional temperature range. Thus, to reverse hypothermia it is necessary only to rewarm this small central portion of the total body mass. The Vitalheat is designed to return these critical organs to within their functional temperature range. The application of negative pressure to specific heat exchange vascular structures (to maximize subcutaneous blood flow) combined with the application of heat to the skin overlying this mechanically-distended vasculature allows the Vitalheat to directly heat the thermal core of a hypothermic human. Venous return carries the heated blood directly from the skin surface to the thermal core. This technique is unique in that it heats the thermal core without requiring heating of the entire body periphery and, thus, dramatically reduces the time and energy required to treat a hypothermic individual.



Dynatherm
MEDICAL, INC.

**PRINCIPLE OF ACTION:
RAPID HEAT TRANSPORT VIA BLOODSTREAM
HAND TO HEART TO VITAL ORGANS...**



Vitalheat™

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Vitalheattm

Just a Few of the Features

- ✓ THREE OPERATIONAL SETTINGS
- ✓ AUTOMATIC TIMER FUNCTION
- ✓ TEMPERATURE RANGE GAUGE
- ✓ VACUUM RANGE GAUGE
- ✓ OVERTEMP & LEAK DETECTION
- ✓ TABLE/FLOOR/IV POLE AND WALL MOUNTING
- ✓ FAST CORE REWARMING
- ✓ MAXIMIZES BODY ACCESSIBILITY
- ✓ NON-INVASIVE
- ✓ COMPACT / MOBILE

The New Standard Designed for Rapid Rewarming

Vitalheat™ the state-of-the-art, non-invasive thermal core warming device designed to rapidly restore normothermia in a hypothermic patient, is a preferred treatment option. Vitalheat is easy to use compared to alternate therapies. It is easily administered, lightweight and compact to permit maximum body accessibility. The combination of the Thermal Exchange Controller and the disposable Hypothermia Warming Mitt respectively will provide the necessary functional elements of vacuum and heat. This device allows trauma care providers a means of delivering quick and effective care to hypothermic individuals.



How it Works

Vitalheat is a non-invasive means of treating hypothermia. Hypothermic individuals are vasoconstricted. Vasoconstriction slows heat loss from the body core, but also impedes the transfer of heat applied to the skin into the body core. Vitalheat creates a direct thermal pipeline between the skin and the body core by circumventing the vasoconstrictive blockade to heat transfer. Uniquely, the TheVitalheat rewarms the critical core regions first, then allows for expansion of the thermal core. It can return the thermal core to functional temperature range in as fast as 15-30 minutes. Vitalheat is so effective because its dynamic combination of heat and vacuum gets heat to the core quickly.

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**Premarket Notification 510(k)
Section 4 – Device Description**

VitalHeat™

4.0	Device Description
4.1	Background and Modification of AcroTHERM
4.2	Summary of Device Features
4.3	Intended Use
4.4	Patient Population
4.5	Contraindications
4.6	Environments of Use
4.7	Power Specifications
4.8	Maintenance
4.9	Accessories
4.10	Materials
4.11	Testing and Risk Analysis
4.12	Operating Temperatures

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**Premarket Notification 510(k)
Section 4 – Device Description**

VitalHeat™



4.0 Device Description

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Section 4 – Device Description

VitalHeat™

Person limits the transfer of heat from superficial surfaces, which can also prevent from the core temperature from increasing. Current methods used in healthcare facilities, such as forced-air rewarming, can be ineffective in overcoming the "vasoconstrictive blockade." The VitalHeat™ efficiently warms the body non-invasively from the inside out, including the vital organs that comprise the majority of the thermal core.

Hypothermia is defined as the condition of a temperature-regulating organism when core temperature is below the set rang specified for the normal active state of the species. Hypothermia has significant clinical consequences, including:

1. Increased risk of cardiac mortality and morbidity.
2. Increased infection rates.
3. Increased recovery time.
4. Increased fluid requirements.

Recovery from cold and decreased core temperature are dependent on an individual's ability to prevent further heat loss from the body core, while generating and/or maintaining as much heat/energy within the body core thermal compartment. When the core temperature falls below the desired set point, involuntary physiological responses occur to prevent further heat loss. Heat flux between the periphery (i.e., skin) and body core is a function of the amount of blood flowing between the core thermal compartment and the periphery (skin), especially the specialized heat transfer areas (palms of the hand, soles of the feet, cheeks, nose, and ears). The flow of blood to the skin is a function of peripheral vasomotor tone. When vasodilated, there is a free exchange of heat between the body core and the periphery. When vasoconstricted, this exchange of heat from the periphery to the body core is restricted.

A reduction in core temperature causes a vasoconstrictive response that is maintained until core temperature returns to the desired normothermic set point of the individual. This response is controlled, at a 4:1 ratio, by the body core temperature, versus the superficial (skin) temperature. Therefore, heating of the skin has only a limited effect on core temperature due to vasoconstrictive blockade resulting from the reduction in core temperature.

The VitalHeat™ approaches the rewarming dilemma by adding sub-atmospheric pressure combined with a thermal load applied to a specialized heat transfer area (hand). By mechanically distending the specialized heat exchange vessels, heat is transferred more efficiently to the body core.

The VitalHeat™ system comprises the following components:

1. Control unit with pre-connected Paddle
2. Disposable Warming Mitt.

Diagrams depicting the two main components and their subassemblies are in Attachment A. Design and performance criteria are found in **TAB #13**.

**Premarket Notification 510(k)
Section 4 – Device Description**

VitalHeat™

Sub Atmospheric Pressure Source:

A key ingredient of the technology is the ability to provide sub-atmospheric pressure in the localized area being treated. In a patient experiencing a reduction in core temperature, the VitalHeat™ acts to increase core body temperature and reduce the physical discomfort by the simultaneous application of heat and sub-atmospheric pressure to the treated area (hand). These areas are documented as primary heat exchangers that the body utilizes to respond to changes in core temperature. In a hypothermic patient, the application of heat alone to these same areas will not efficiently increase core body temperature due to the vasoconstrictive blockade of the blood vessels in the periphery.

The VitalHeat™ is designed to apply of 40 +/-5-mmHg sub-atmospheric pressure to the treated area. Treatment of a single appendage is sufficient to increase the heat transferred to the body core. This low level of sub-atmospheric pressure manually creates vasodilation in the treated appendage, thus allowing the thermal load applied to the skin to be more efficiently transferred to the blood stream and, ultimately, the body core.

The source of the sub-atmospheric pressure is a vacuum pump incorporated in the control unit.

Temperature Measurement:

In clinical tests performed with the Acrotherm cleared under K003368 thermocouple inserted into the ear was used to measure tympanic temperature. Tympanic temperature is considered to be an accepted measure of core body temperature. It is anticipated that routine methods (e.g., infrared thermometers used in the ear) will be the method used by most clinicians in assessing core body temperature. Because of the general availability of such devices, it is not anticipated that a body temperature-measuring device will be included with the VitalHeat™ system.

Safety Features

Controls to prevent overheating of the patient:

As the VitalHeat™ system rewarms cold patients, the thermoregulatory system of the body self-regulates to adapt vasomotor tone to changes in core temperature. As core temperature increases, the periphery circulatory system specializing in heat transfer increases the vasodilation, allowing for the effective elimination of excess heat. In the event the body is maximally vasodilated and heat is still applied, the patient will perspire to assist in the elimination of excess heat. Once core body temperature has been returned to an individual's set point, the body's own physiologic thermoregulatory system adapts to maintain that set point.

A series of single logic controls work together to ensure that the system operates safely.

**Premarket Notification 510(k)
Section 4 – Device Description**

VitalHeat™

4.1 Background and Modification of AcroTherm

The benefit of warming devices in the clinical setting for managing a patient's temperature has been established. These benefits include increased healing response, decreased cardiac morbidity, increased patient comfort and reduced recovery time.

The Vital Heat™ temperature management device is a modification of the 510(K) device, the AcroTherm- K003368. The Vital Heat™'s technology for applying a sub-atmospheric pressure on a appendage and applying heat is the same as the Acrotherm

**Premarket Notification 510(k)
Section 4 – Device Description**

VitalHeat™

Section #11 includes drawings of the VitalHeat™. Below is a summary of the device features

4.2 Summary of Device Features

Summary of Device Features

PRODUCT	VitalHeat™
Intended Use	Patient Temp. Management
Type	Negative Pressure/ Water Heated Aluminum Dome
Pressure Device	Yes-sub-atmospheric
Sub-atmospheric pressure (mmHg)	40±5
Electric (AC)	Yes
Temp. Range	(b)(4) Confidential and Proprietary Information
Application Site	Distal Limb (hand)
Disposable Type	Single use Mitt
Control System	
Controller Type	Micro-logic/hardware
Size	14x6x5 in
Weight	15 lb
Mobility	Hand-held
Water Tank	(b)(4) Confidential and Proprietary Information
Safety	
High Temperature Alarm	Yes
Water Flow Alarm	Yes
Sub-Atmospheric Pressure Alarm	Yes
Electrical Safety	Yes UL 2601-1 and IEC 601-1-2

4.3 Intended Use

The VitalHeat™ is a compact and portable warming device for use in healthcare facilities to help recover patients from the discomfort and consequences of lowered body temperature. This device combines sub-atmospheric pressure and heat on one heat-exchanging extremity.

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**Premarket Notification 510(k)
Section 4 – Device Description**

VitalHeat™

4.4 Patient Population

The system is for use with patients 18 years of age and older.

4.5 Contraindications

The VitalHeat™ is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

4.6 Environments of use

Health care facilities, including hospitals, ICUs, Ors, Ers, PACU, burn units and medical/surgical floors.

4.7 Power specifications

The heater and power supply are operated under 120V AC. The power supply provides 12V DC power to the pumps for vacuum and water.

4.8 Maintenance

The heat exchanger paddle does not require maintenance. Periodic inspection for the function of the latch should be made. Cleaning of the paddle and is performed when needed with a mild hypoallergenic soap and water. A mild, non-toxic disinfectant spray can also be used.

The control unit and tubing set should be periodically inspected for damage. See **Tab # 10** for User's Manual Instructions.

4.9 Accessories

- Wall Mount

Drawings of the accessory have been included in **Tab # 12**.

4.10 Materials

See **Tab #6**, Biocompatibility, for a table of materials.

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**Premarket Notification 510(k)
Section 4 – Device Description**

VitalHeat™

4.11 Testing and Risk Analysis

Testing of the device has been composed of two groups of tests: Functional and Safety.

Functional/bench testing:

We have performed several functional bench tests.

The Design Criteria and Test Report are located behind **Tab #13**.

Safety Testing:

Beside the safety testing also includes our bench testing. Electrical safety and EMC (electromagnetic compatibility) testing performed by Underwriters Laboratories (UL). Compliance to UL2601-1, and 601-1-2 will be certified.

Mechanical safety will be determined through testing from UL in combination with in-house testing and external packaging tests according to ISTA Procedure 2A.

Risk Analysis was completed. This report is located behind **Tab # 14**.

4.12 Operating Temperature

The materials utilized in the warming mitt, tubing set, control unit, and disposables can be used within the following environmental temperature range: 5°C to 50°C.

**Premarket Notification 510(k)
Section 5 – Comparison to Predicates**

VitalHeat™

5.0	Comparison to Predicates
5.1	Discussion of the Comparison and Differences
5.2	Substantial Equivalence
5.3	Predicate Information
Table 5.01	Comparative Table

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Premarket Notification 510(k)
Section 5 – Comparison to Predicates

VitalHeat™

5.1 Discussion of the Comparison and Differences

The VitalHeat™ is a modification of a 510(k) cleared thermal regulating system, the AcroTherm™ K003365. The modified device utilizes a circulating water paddle system, similar to the systems of other devices in this classification. **Table 5.01** summarizes the major elements of comparison for the modified device and the two predicate devices.

The VitalHeat™, like the AcroTherm™, applies a combination of heat and sub-atmospheric pressure to a distal limb. Both devices have the limb and heat source enclosed in a mitt. The main difference between the VitalHeat™ and the AcroTherm™ is the heat source; supplies heat through a water perfusion pad, which maintains a constant temperature within a specified range. The temperature range of both devices is the same. In addition, The VitalHeat™ has a separate control unit and connecting hoses to supply the heated water and sub-atmospheric pressure to the mitt.

The VitalHeat™ system has similar but improved design differences between the predicates. AcroTherm™ used an open water loop system, the water was added to the tank thru a removable cap on the control unit. The heated water flowed thru the tubing to the warming chamber. Inside the chamber were two (2) water perfusion pads, in contact to the patients hand and forearm both top and bottom. The warming mitt was also detachable from the tubing set thru a connector. We found thru clinicals and customer interface that filling the system with water and keeping it clean was difficult.

VitalHeat™ is a closed loop system water is added at the factory and unit is shipped to the customer filled. Unlike AcroTherm™ The VitalHeat™ uses just palm side of the hand. The heated water is an aluminum paddle heatsink. The design of this heatsink is shaped to provide maximum hand contact. This design proved during testing to increase heat transfer over AcroTherm™ type water perfusion pads.

Hands vs. Distal Limb

The palm of your hands and feet are the heat exchangers of the body. The current design provides better heat transfer from heat source to the hand. Thru testing we found the palm of the hand was all that is needed to provide a change in patients temperature.

Water Tank 200ML vs. 400 – 500 ML

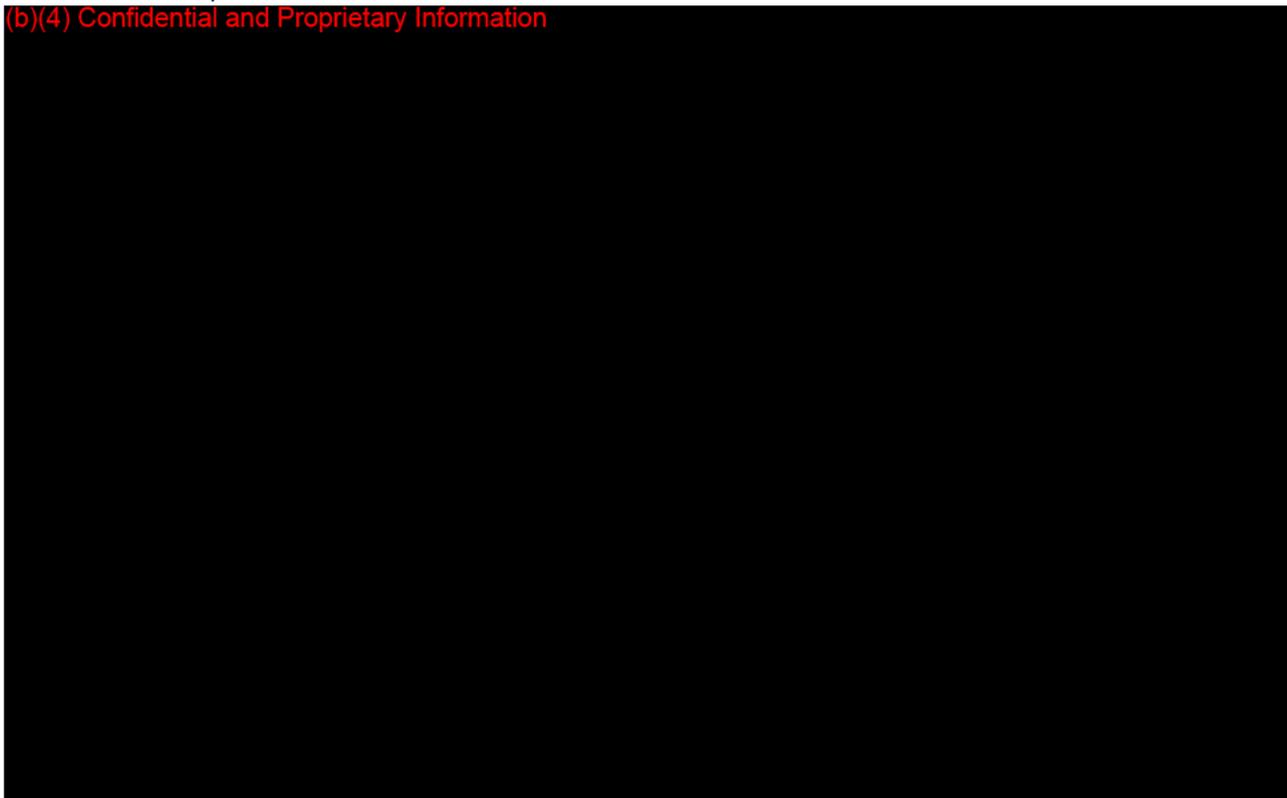
The Volume of water was reduced in the tank; do to the change from water perfusion pads to the domed paddle in The VitalHeat™.

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Flow Rate > 1000 MI/Min. vs. < 500 MI/Min

The flow rate was increased to 1000 MI/Min. to enhance thermal response of the temperature control loop.

(b)(4) Confidential and Proprietary Information



5.2 Substantial Equivalence

The VitalHeat™ is viewed as substantially equivalent to the predicate devices since it:

1. Has the same intended uses:
 - The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by warming their body core. This accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

2. Has the same environments for use:
 - Hospital/Healthcare environments where patient temperature management is necessary.

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Premarket Notification 510(k)
Section 5 – Comparison to Predicates

VitalHeat™

3. Has design features present in both predicates:

- Warming Mitt – AcroTherm™
- Water perfusion pad – AcroTherm™
- Separate control panel for control and monitoring of the system – AcroTherm™
- Warming Mitt which applies heat and sub-atmospheric pressure simultaneously – AcroTherm™
- Uses heated water as a thermal medium for application of heat through the thermal pad – AcroTherm™

4. Is made of similar materials:

- All patient contacting materials are biocompatible and have passed USP Class VI testing.

5.3 Predicate Information

TAB #15 and TAB #16 contains information on the two predicates devices.

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Premarket Notification 510(k)
Section 5 – Comparison to Predicates

VitalHeat™

Table 5.01 Comparative Table

Product Features and Benefits

Features	Benefits
<ul style="list-style-type: none"> • Product is applied to hand appendage 	<ul style="list-style-type: none"> • Maximizes patient access and ability to perform standard care of patient.
<ul style="list-style-type: none"> • Easy 5 steps 	<ul style="list-style-type: none"> • One Size • Preprogrammed functions; one button activates system • Quick set up
<ul style="list-style-type: none"> • Combination with water perfusion pad • Combination of vacuum and heated water thermal exchange paddle. 	<ul style="list-style-type: none"> • Maintain temperature in OR and warm up in PACU.
<ul style="list-style-type: none"> • Cover 95% human anatomical size. 	<ul style="list-style-type: none"> • One size fits all
<ul style="list-style-type: none"> • Multiple automatic shut-off systems for increase patient safety. 	Temperature, pressure monitored and incorporate alarms for improper functioning
<ul style="list-style-type: none"> • Easy to read indicators 	<ul style="list-style-type: none"> • Increase product efficacy
<ul style="list-style-type: none"> • Blown hot air on entire body vs. warm up on hand 	<ul style="list-style-type: none"> • Reduce uncomfortable convection hot air
<ul style="list-style-type: none"> • Pre-op and Intra-op use 	<ul style="list-style-type: none"> • Keep warm during peri operative procedure
<ul style="list-style-type: none"> • Small disposable 	<ul style="list-style-type: none"> • Cost saving
<ul style="list-style-type: none"> • Low cost and easy to apply disposable 	<ul style="list-style-type: none"> • Cost and time save
<ul style="list-style-type: none"> • Provides efficient heat transfer using water perfusion heat paddle. 	<ul style="list-style-type: none"> • Maximizes heat transfer area of the body to deliver heat to the core
<ul style="list-style-type: none"> • Closed water circulation system 	<ul style="list-style-type: none"> • Limited water refilling and maintenance needed
<ul style="list-style-type: none"> • Easy to connect the control unit to an IV pole or a wall mount 	<ul style="list-style-type: none"> • Goes with the patient during transport

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**Premarket Notification 510(k)
Section 5 – Comparison to Predicates**

VitalHeat™

04-05-04

John Chen

5.1 Discussion of the Comparison and Differences

The VitalHeat™ is a modification of a 510(k) cleared thermal regulating system, the AcroTherm K003365. The modified device utilizes a circulating water paddle system, similar to the systems of other devices in this classification. **Table 5.01** summarizes the major elements of comparison for the modified device and the two predicate devices.

The VitalHeat™, like the AcroTherm, applies a combination of heat and sub-atmospheric pressure to a distal limb. Both devices have the limb and heat source enclosed in a mitt. The main difference between the VitalHeat™ and the AcroTherm is the heat source; supplies heat through a water perfusion pad, which maintains a constant temperature within a specified range. The temperature range of both devices is the same. In addition, The VitalHeat™ has a separate control unit and connecting hoses to supply the heated water and sub-atmospheric pressure to the mitt.

The separate control unit and hoses for supplying a heated water supply to a thermal pad is similar to the AcroTherm. The thermal pad is a blanket for enveloping portions or the entire body of the patient. The AcroTherm water perfusion pad envelops only a portion of a limb (the hand). In addition, therefore, the VitalHeat™ is a modification of an existing approved device using the technology of another existing approved device in the same classification.

5.2 Substantial Equivalence

The VitalHeat™ is viewed as substantially equivalent to the predicate devices since it:

1. Has the same intended uses:
 - Intended for patient temperature management
2. Has the same environments for use:
 - Hospital/Healthcare environments where patient temperature management is necessary.

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**Premarket Notification 510(k)
Section 5 – Comparison to Predicates**

VitalHeat™

04-05-04

[Handwritten signature]

1. Has design features present in both predicates:

- Warming Mitt – AcroTherm
- Water perfusion pad – AcroTherm
- Separate control panel for control and monitoring of the system – AcroTherm
- Warming Mitt which applies heat and sub-atmospheric pressure simultaneously – AcroTherm
- Uses heated water as a thermal medium for application of heat through the thermal pad – AcroTherm

2. Is made of similar materials:

- All patient contacting materials are biocompatible and have passed USP Class VI testing.

5.3 Predicate Information

TAB #15 and TAB #16 contains information on the two predicate devices.

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**Premarket Notification 510(k)
Section 5 – Comparison to Predicates**

VitalHeat™

3-31-04

[Handwritten signature]

3. Has design features present in both predicates:

- Warming Mitt – AcroTherm
- Water perfusion pad – AcroTherm
- Separate control panel for control and monitoring of the system – AcroTherm
- Warming Mitt which applies heat and sub-atmospheric pressure simultaneously – AcroTherm
- Uses heated water as a thermal medium for application of heat through the thermal pad – AcroTherm

4. Is made of similar materials:

- All patient contacting materials are biocompatible and have passed USP Class VI testing.

5.3 Predicate Information

TAB #15 contains information on the two predicate devices.

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**Premarket Notification 510(k)
Section 5 – Comparison to Predicates**

VitalHeat™

04-05-04
[Signature]

Table 5.01 Comparative Table

Product Features and Benefits

Features	Benefits
<ul style="list-style-type: none"> Product is applied to hand appendage 	<ul style="list-style-type: none"> Maximizes patient access and ability to perform standard care of patient.
<ul style="list-style-type: none"> Easy 5 steps 	<ul style="list-style-type: none"> One Size Preprogrammed functions; one button activates system Quick set up
<ul style="list-style-type: none"> Combination with water perfusion pad Combination of vacuum and heated water thermal exchange paddle. 	<ul style="list-style-type: none"> Maintain temperature in OR and warm up in PACU.
<ul style="list-style-type: none"> Cover 95% human anatomical size. 	<ul style="list-style-type: none"> One size fits all
<ul style="list-style-type: none"> Multiple automatic shut-off systems for increase patient safety. 	<ul style="list-style-type: none"> Temperature, pressure monitored and incorporate alarms for improper functioning
<ul style="list-style-type: none"> Easy to read indicators 	<ul style="list-style-type: none"> Increase product efficacy
<ul style="list-style-type: none"> Blown hot air on entire body vs. warm up on hand 	<ul style="list-style-type: none"> Reduce uncomfortable convection hot air
<ul style="list-style-type: none"> Pre-op and Intra-op use 	<ul style="list-style-type: none"> Keep warm during peri operative procedure
<ul style="list-style-type: none"> Small disposable 	<ul style="list-style-type: none"> Cost saving
<ul style="list-style-type: none"> Low cost and easy to apply disposable 	<ul style="list-style-type: none"> Cost and time save
<ul style="list-style-type: none"> Provides efficient heat transfer using water perfusion heat paddle. 	<ul style="list-style-type: none"> Maximizes heat transfer area of the body to deliver heat to the core
<ul style="list-style-type: none"> Closed water circulation system 	<ul style="list-style-type: none"> Limited water refilling and maintenance needed
<ul style="list-style-type: none"> Easy to connect the control unit to an IV pole or a wall mount 	<ul style="list-style-type: none"> Goes with the patient during transport

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**Premarket Notification 510(k)
Section 6.0 Biocompatibility and Materials**

VitalHeat™

6.0 Biocompatibility and Materials

**Premarket Notification 510(k)
Section 6 – Biocompatibility and Materials**

VitalHeat™

BIOCOMPATIBILITY

All the materials utilized in construction of the VitalHeat™ device are commonly utilized in medical devices. Any material which has potential for extended or intimate patient contact is biocompatible and has passed USP Class VI plastics testing. See section 4.11 (and Table below) for a listing of components and their material composition.

Location	Component	Material	Patient Contact	Evaluation
Disposable	Mitt, Lower Mitt, Upper	(b)(4) Confidential and Proprietary Information - Draft	Direct	(b)(4) Confidential and Proprietary Information - Draft
Heating Paddle	Heating Dome		Incidental	
Disposable	Diaphragm, Mitt		Direct	
Disposable	Gasket, Mitt/Paddle Interface		Incidental	
Disposable	Vacuum Cord Gasket		Incidental	
Disposable	Hand Strap Assembly, Mitt		Direct	
Disposable	Mitt Hinge		Incidental	
Disposable	Mitt Filter Assembly		Direct	
Disposable	Mitt Bag – 10 x 12 Mitt Package Label		None	
Disposable	Product ID Label		Incidental	
Disposable	Mitt IFU Protective Sheet		None	
Disposable	Seal Assembly		Direct	
Tubing Set	Outer Insulation		Incidental	
	Inner Tubing		None	
Control Unit	Housing		None/ Incidental	

Device Certification

(b)(4) Confidential and Proprietary Information - Draft

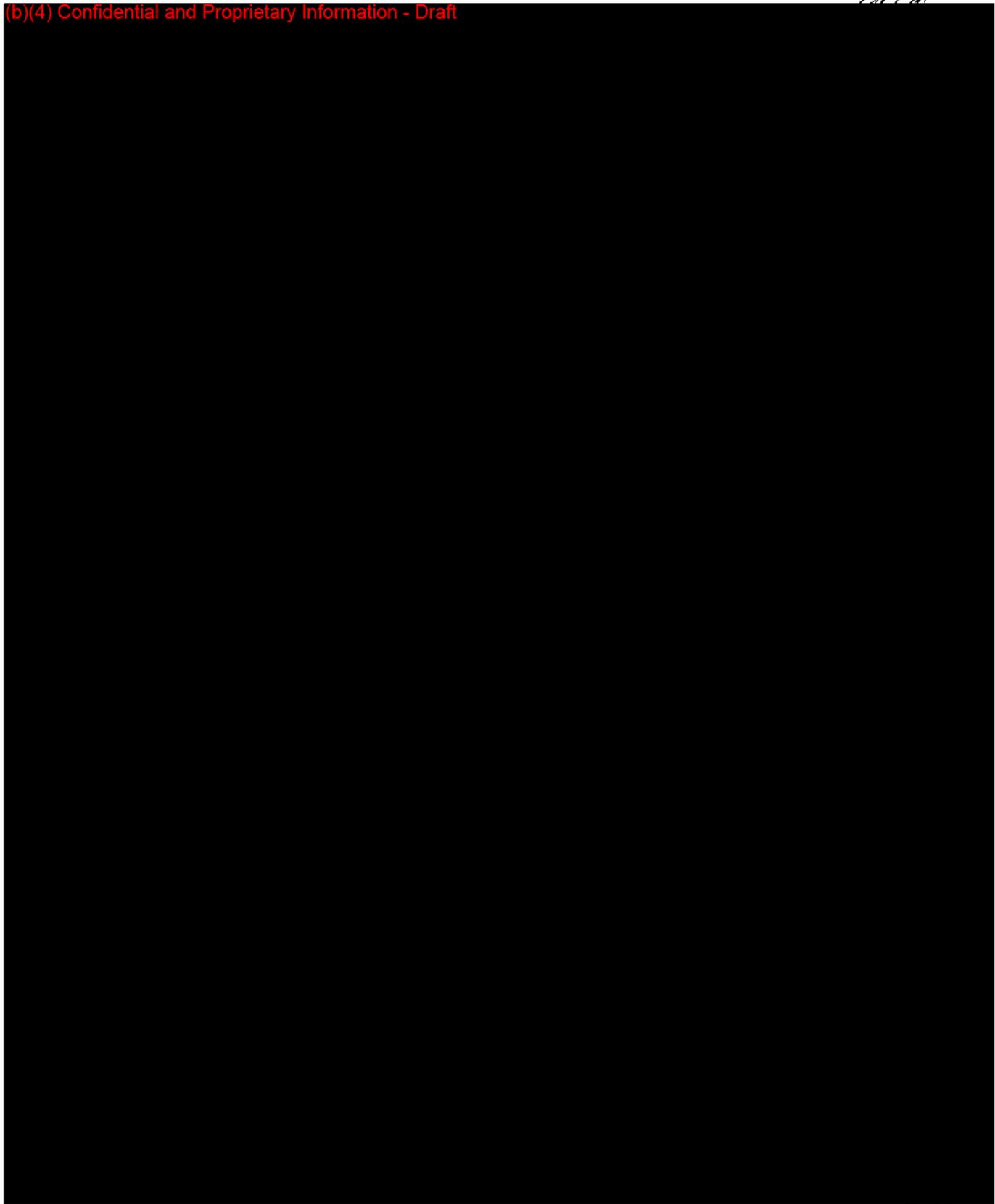
* Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
Same Material as Acrotherm Device **K003368**

**Premarket Notification 510(k)
Section 6 – Biocompatibility and Materials**

VitalHeat™

03-31-04
1/1/10

(b)(4) Confidential and Proprietary Information - Draft



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**Premarket Notification 510(k)
Section 7 – Sterilization Information**

VitalHeat™

7.0 Sterilization Information

The device is sold non-sterile.

The User's Manual describes the cleaning methods, see **TAB #10**.

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Premarket Notification 510(k)
Section 8 – Software Verification and Validation

VitalHeat™

8.0 Software Verification and Validations

The product does not operate with any software.

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**Premarket Notification 510(k)
Section 9 – Specific Standards**

VitalHeat™

9.0 Performance Standards

There are no performance standards established under Section 5.1.4. However, bench testing has been performed as part of the design control process. This testing includes the evaluation of the following components:

Control Unit

- Water temperature and alarms
- Water flow and alarms
- Mitt vacuum and alarms
- Electrical Safety
- Paddle Heatsink

Disposable Warming Mitt

- Wrist Seal

See **TAB # 13** for the design and performance criteria.

In all cases the devices met their established performance criteria for their intended use and environments of use.

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**Premarket Notification 510(k)
Section 10 – Operator's Manual**

VitalHeat™

10.0 Operator's Manual

Vital*Heat* TM

OPERATION MANUAL

DRAFT



819 Mitten Road, Suite 42. Burlingame, CA 94010
650.777.4361
Sales@DynathermMedical.com

Table of Contents

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1. Precautions, Indications & Contradictions / General Description.....	3 - 4
2. Components of VitalHeat™	5 -6
3. Instructions for Use – VitalHeat™	7 - 8
4. Care	9
5. Storage.....	9
6. Troubleshooting Guide.....	10
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Precautions

1. The VitalHeat™ is a body core-rewarming device for the treatment of hypothermia.
2. The VitalHeat™ should not be used without the complete knowledge of the Instructions For Use.
3. The VitalHeat™ must be monitored during use.
4. In all cases, local practice and the authority of the physician take precedence over the procedures described here.
5. Do not operate VitalHeat™ under the following conditions
 - Improper functioning
 - Damaged cord, tubing set or plug.
 - Damage to the control unit and/or warming chamber that affects the functionality of the system.
6. To discontinue use of the VitalHeat™, turn the main switch off, and then remove plug from power outlet.
7. Do not disassemble the VitalHeat™. If the VitalHeat™ is disassembled, any warranty in effect will be voided.

Indications / Contraindications

INDICATIONS FOR USE:

The VitalHeat™ is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and a thermal (heat) load to a distal appendage (hand).

CONTRAINDICATIONS:

VitalHeat™ is contraindicated for use in the following patients:

- Patients under 18 years of age
- Patients with peripheral vascular disease

CAUTION:

Federal law restricts this device to the sale by or on the order of a physician.

General Description of the VitalHeat™

Efficient -	capable of rewarming body core rapidly
Single use Mitt -	Disposable mitt is only part that contacts the patient
Non-invasive -	No skin puncture
Comfortable -	May prevent painful shivering and provide soothing warmth
Compact -	Simple application to hand of the patient

The VitalHeat™ is a body core-rewarming device that provides a non-invasive technique designed to reverse hypothermia. The VitalHeat™ can reverse hypothermia in as short a time as 15 minutes (e.g. mild to moderate hypothermia), depending on the severity of the hypothermia; typical application time is 35 minutes.

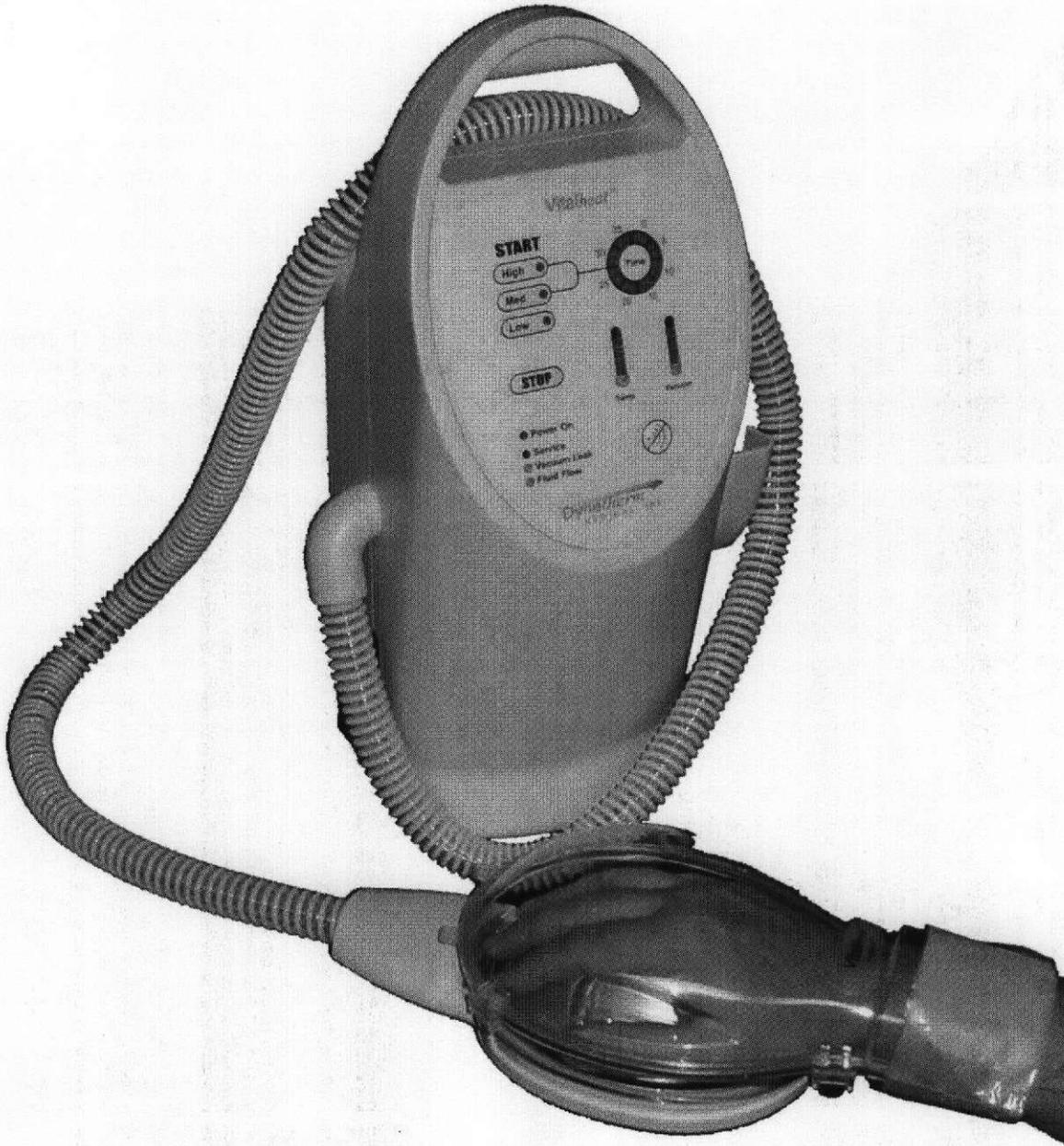
The thermal core of a human is comprised of the internal organs that function optimally in a narrow temperature range. The organs that make up the thermal core represent only a small portion of the total body mass (less than 10%). Hypothermia is the conditions when the temperature of the thermal core falls below the functional temperature range. Thus, to reverse hypothermia only a small portion of the total body mass must be rewarmed. Our thermoregulatory system is designed to maintain these critical organs within their functional temperature range. The application of negative pressure to the specific heat exchange vascular structures (to maximize subcutaneous blood flow) combined with the application of heat to the skin overlying this mechanically distended vasculature allows the VitalHeat™ to directly heat the thermal core of a hypothermic individual. Venous return carries the heated blood directly from the skin surface to the thermal core. This technique is unique in that it heats the thermal core without requiring heating of the entire body periphery and, thus, dramatically reduces the time and energy required to treat a hypothermic individual.

Components of the VitalHeat™

A. Disposable warming Mitt with Wrist Seal



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B. Heat exchanger Paddle and C ontrol Unit.

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Instructions For Use VitalHeat™

Note:

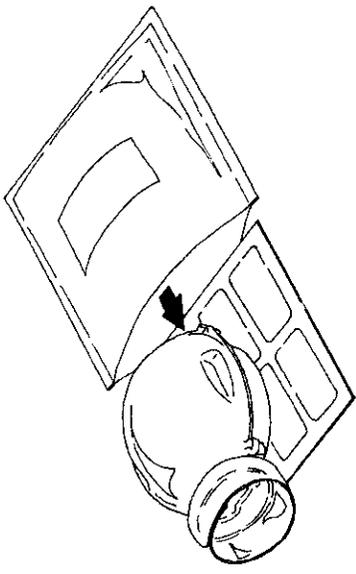
Do not remove the Hypothermia Warming Mitt Wrist Seal from the protective package until the time of application.

1. Uncoil the heat exchange paddle from the controller and lay it on a flat surface.
2. Remove the mitt from its protective bag. Read IFU and discard IFU.
3. Snap the mitt bottom onto the paddle.
4. Place the patients hand over the heater dome.
5. Snap the lid close and confirm that the hand strap is holding the patient's hand lightly on the heater dome.
6. Confirm that all four lid latches are properly secured.
7. Remove protective backing from wrist seal and apply to the patient's wrist.
8. Power on the controller.
9. Select the run mode (High/Medium/Low)
10. Confirm the vacuum is OK. The vacuum should pump down to the green indicator in less than 20 seconds
11. Confirm the heater is warming up the device. The temperature indicator should show a rise in less than one minute.
12. No news is good news. If you don't hear or see an alarm, all is well.

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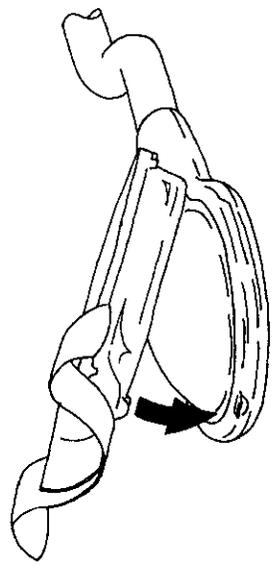
Vitalheattm INSTRUCTIONS FOR USE - Quick Reference Guide - Warming Mitt

1



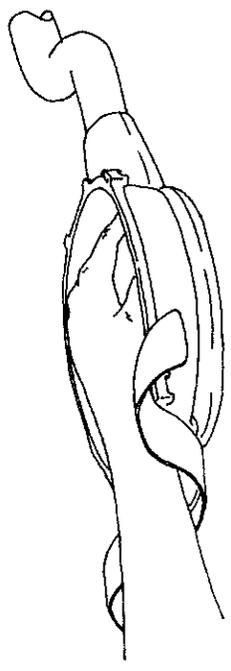
Remove Mitt and Quick Reference Guide from Bag

2



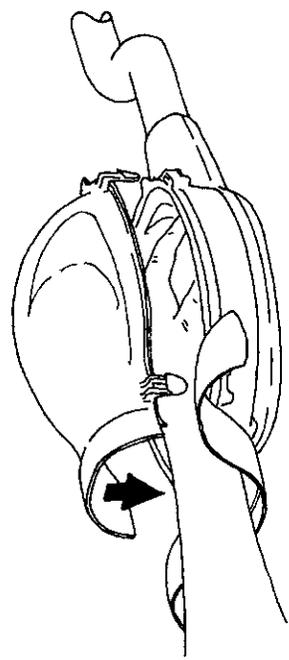
Remove Upper Half of Mitt and Toe (Insert) Lower Half of Mitt into the Paddle Assembly. Tilt Down onto the Latch of Paddle.

3



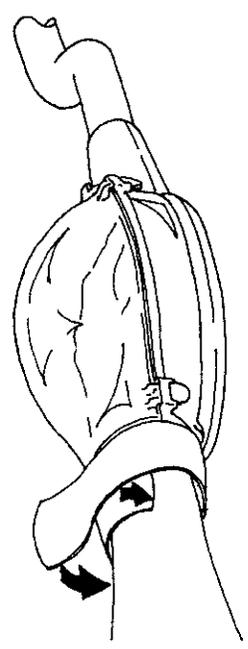
Place Patient's Hand onto the Dome of the Paddle.

4



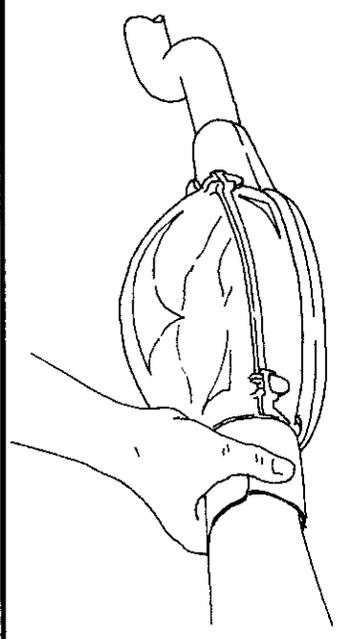
Assemble Top Half of Mitt, Pressing Firmly to Engage Catches.

5



Remove Release Liner from Hydrogel Strap and Wrap Around Patient's Wrist.

6



Firmly Seal Hydrogel to Patient's Wrist and Initiate Controller as Directed.

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Care of the VitalHeat™

The Thermal Exchange Paddle can be cleaned using a standard medical device cleaning fluid, such as denatured alcohol.

CAUTION: Do not immerse the product in liquid.
Do not autoclave.

Storage of the VitalHeat™

It is recommended that the VitalHeat™ System be stored in a secure area free of dust or other contaminants. The disposable, single use Hypothermia Warming Mitt / Wrist Seal should be kept in its factory packaging.

The Hypothermia Mitt/Wrist Seal (Catalog Number 10-1001) should be stored at temperatures between 5°C to 50°C.

Troubleshooting Guide

Problem	Probable Cause	Suggestions to Repair
No power / no lights	<ul style="list-style-type: none"> • Blown fuse 	<ul style="list-style-type: none"> • Check power switch is on • Check for blown fuses
Low Fluid Flow light on	<ul style="list-style-type: none"> • Obstruction in umbilical cord • Too little water in loop 	<ul style="list-style-type: none"> • Check hose for kinks • Check fluid level in the heater tank is above the fill line • Listen for sound of the water pump running • If problem persists contact an authorize service representative
Weak Vacuum light	<ul style="list-style-type: none"> • Poor wrist seal • Poor mitt to paddle seal • Faulty pressure sensor • Faulty vacuum pump 	<ul style="list-style-type: none"> • Check application of the Hydrogel seal around the wrist. • Check the mitt is fully engaged in the paddle clamp • If the mitt seems to have vacuum, it is probably the pressure sensor • Contact an authorize service representative
Mitt does not warm up	<ul style="list-style-type: none"> • Faulty heater 	<ul style="list-style-type: none"> • Contact an authorize service representative

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Reorder Catalog Numbers:

Place orders with: Dynatherm Medical Inc.
819 Mitten Road, Suite 42
Burlingame, Ca. 94010
Phone: 650.777.4361
Fax: 650.777.4370
E-mail: sales@DynathermMedical.com

CATALOG NUMBER	QUANTITY	ITEM DESCRIPTION
VH-1020	10 ea/case	Hypothermia warming mitt/Seal (single use)
VH-1050	1 each	VitalHeat™ Starter Kit. 1 Controller 10 Mitts

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**Premarket Notification 510(k)
Section 11 – Labeling - Device**

VitalHeat™

11.1 Control Unit Labeling

11.2 Warming Mitt Labeling

11.3 Mitt Package Label

11.4 Mitt IFU Protective Sheet

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Premarket Notification 510(k)
Section 11 – Labeling Device

VitalHeat™

11.1 Control Unit Labeling


VitalHeat™
PATIENT WARMING DEVICE

CONTROL UNIT
Cat. No. VH-1050
Serial No.:
Input 120 V 60 Hz

Caution: Federal Law restricts this device
To sale by or on the order of a
Physician.

Dynatherm Medical, Inc.
819 Mitten Rd, Suite 42
Burlingame, CA 94010
Phone: (650) 777-4361
Fax: (650) 777-4370
www.dynathermmedical.com
Made in U.S.A

E710-0002 Rev 1

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Premarket Notification 510(k)
Section 11 – Labeling Device

VitalHeat™

11.2 Warming Mitt Labeling

Dynatherm

VitalHeat™
PATIENT WARMING DEVICE
WARMING MITT
Cat. No. VH-1020
Serial No.:
Contraindications:

- 1) Patients under 18 years of age.
- 2) Patients with Peripheral Vascular Disease.

Caution: Federal Law restricts this device
To sale by or on the order of a
Physician.

Dynatherm Medical, Inc.
819 Mitten Rd, Suite 42
Burlingame, CA 94010
Phone: (650) 777-4361
Fax: (650) 777-4370
www.dynathermmedical.com
Made in U.S.A

E710-0001 Rev 1

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**Premarket Notification 510(k)
Section 11 – Labeling - Device**

VitalHeat™

11.3 Mitt Package Labeling

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**Premarket Notification 510(k)
Section 11 – Labeling - Device**

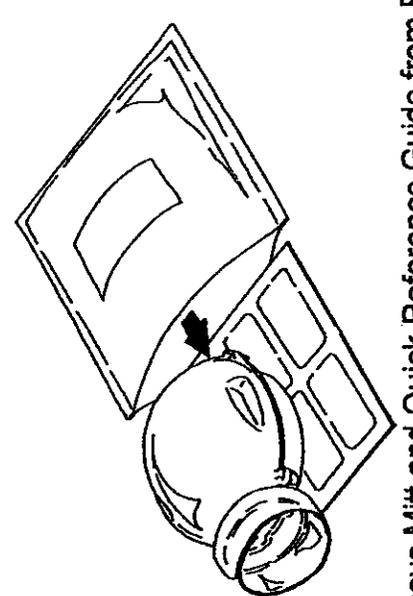
VitalHeat™

11.4 Mitt IFU Protective Sheet

274

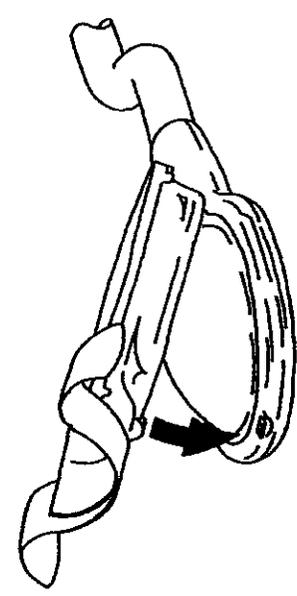
Quick Reference Guide - Warming Mitt

1



Remove Mitt and Quick Reference Guide from Bag

2



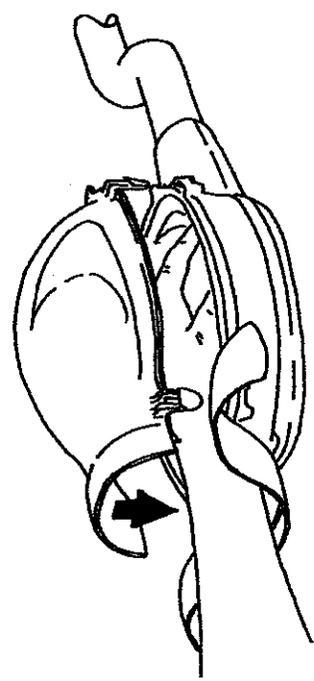
Remove Upper Half of Mitt and Toe (Insert) Lower Half of Mitt into the Paddle Assembly. Tilt Down onto the Latch of Paddle.

3



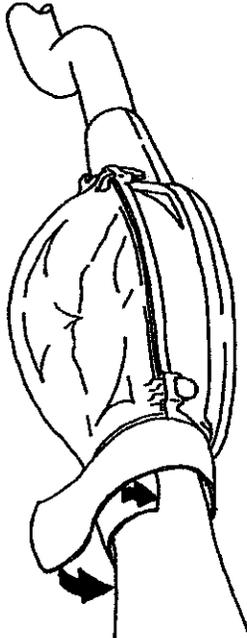
Place Patient's Hand onto the Dome of the Paddle.

4



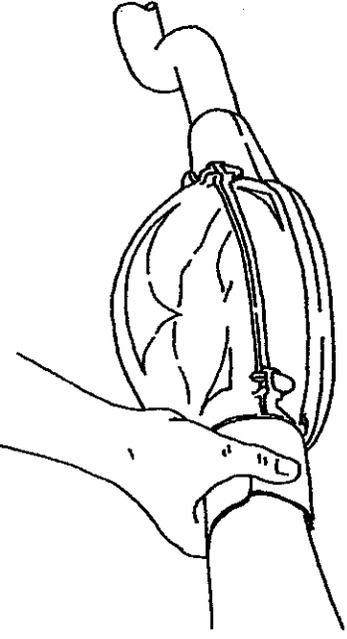
Assemble Top Half of Mitt, Pressing Firmly to Engage Catches.

5



Remove Release Liner from Hydrogel Strap and Wrap Around Patient's Wrist.

6



Firmly Seal Hydrogel to Patient's Wrist and Initiate Controller as Directed.

**Premarket Notification 510(k)
Section 12 – Drawings of Proposed Device**

VitalHeat™

12.1 VitalHeat™ Bill of Materials

12.2 VitalHeat™ PC Controller Board

12.3 Block Diagrams

12.4 Front Panel

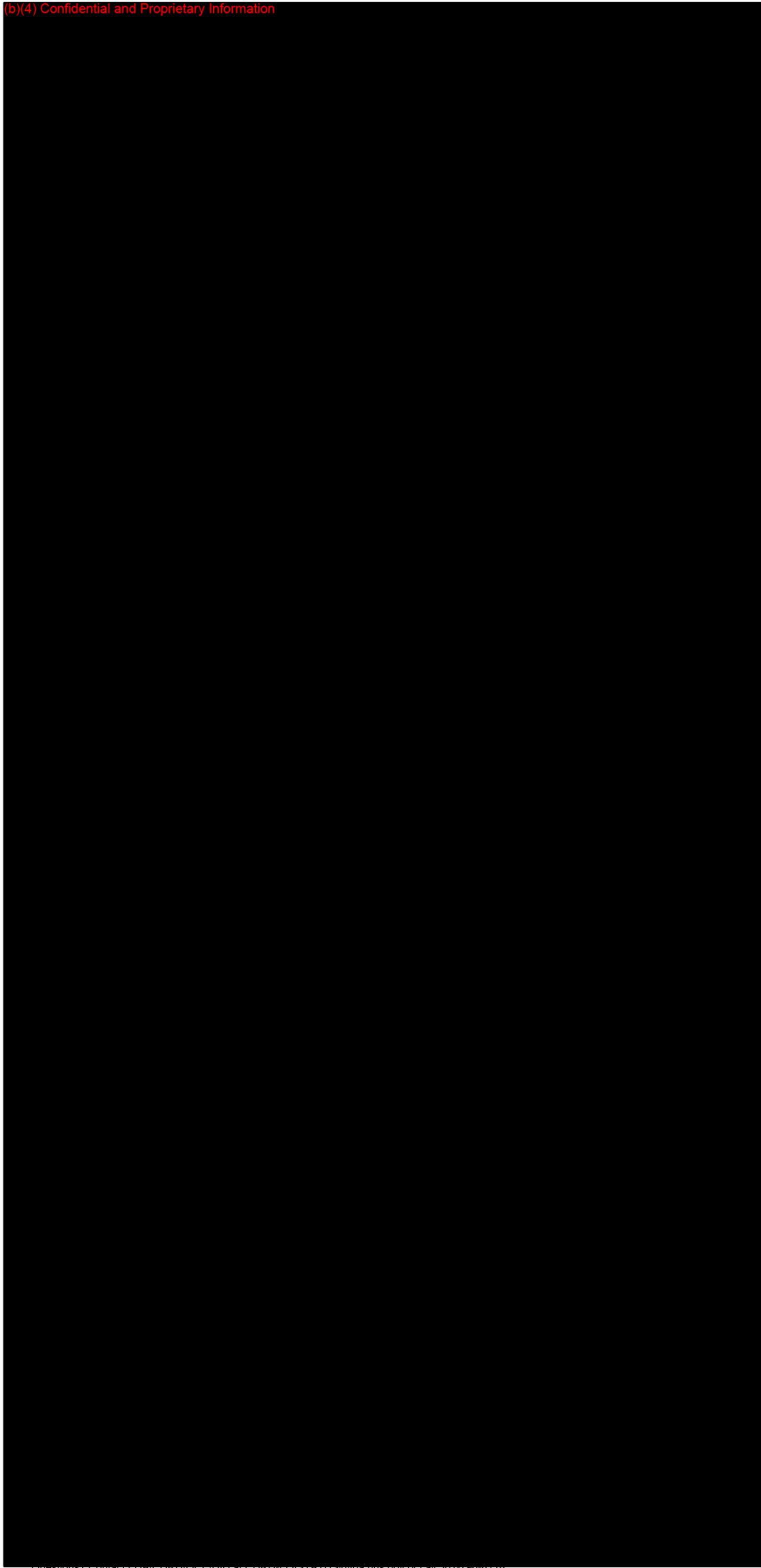
12.5 Water Tank Assembly

12.6 Controller Sub Assembly

12.7 Paddel Sub Assembly

12.8 Mitt Assembly

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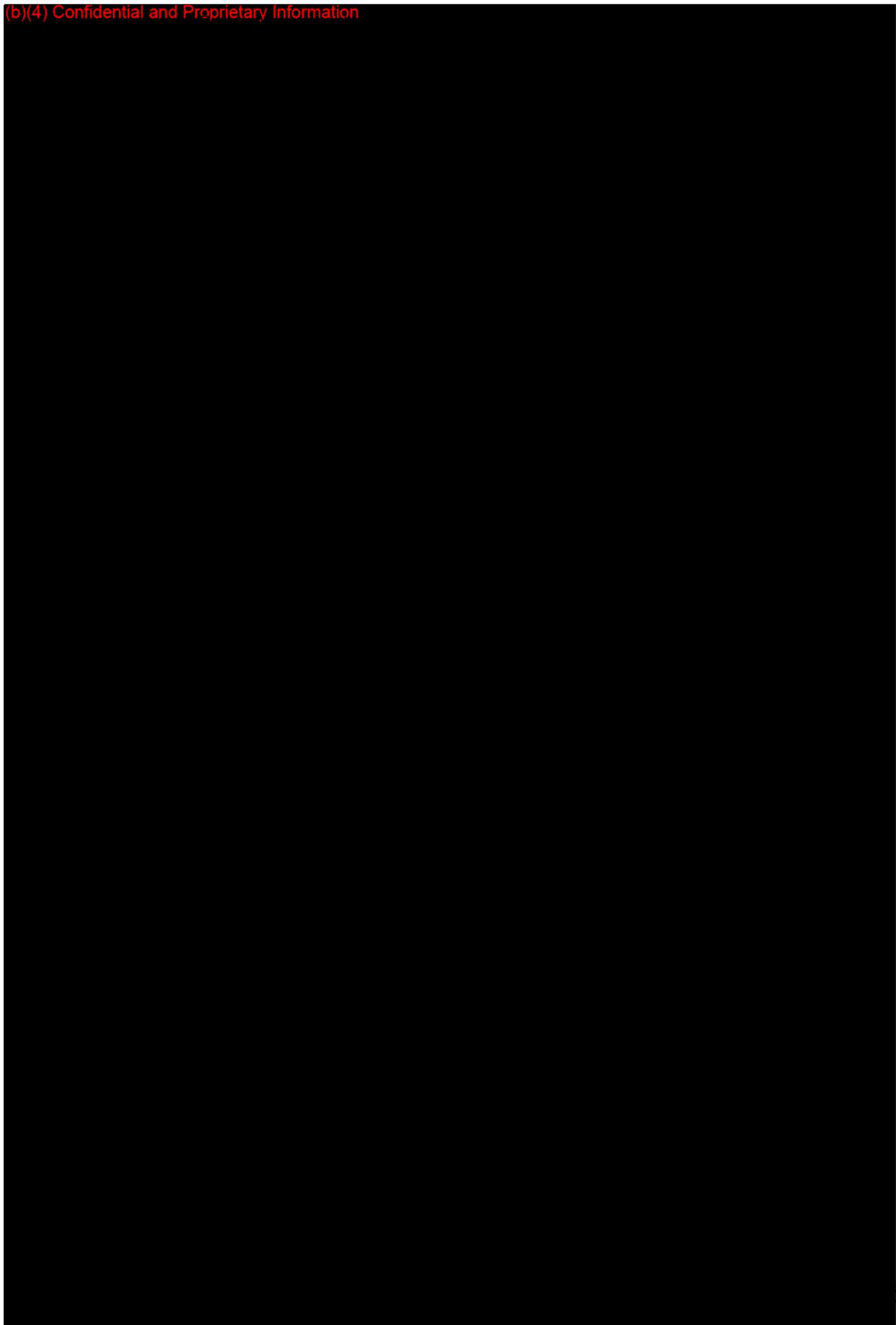


**Premarket Notification 510(k)
Section 12 – Drawings of Proposed Device**

VitalHeat™

12.2 VitalHeat™ PC Controller Board

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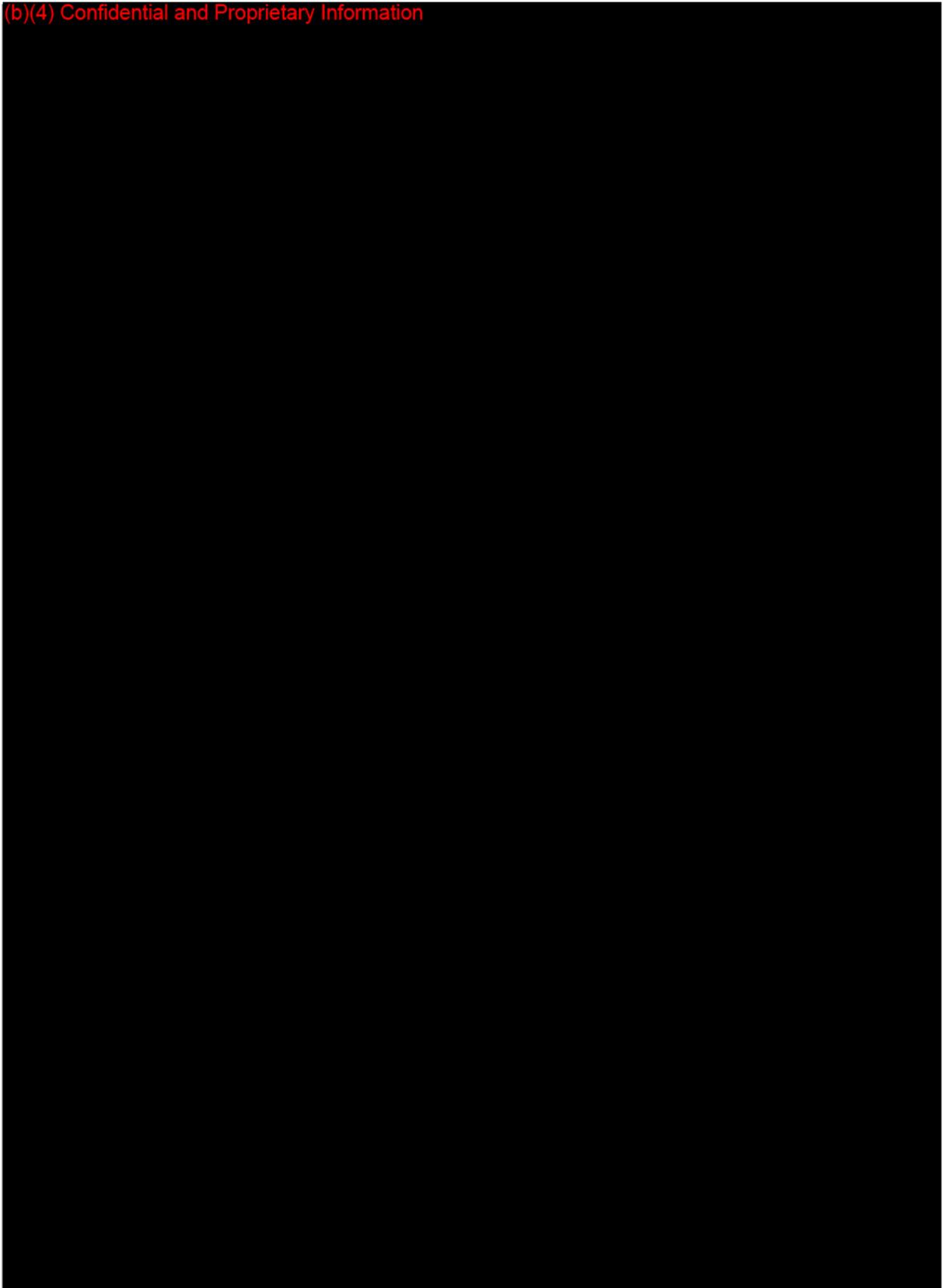


**Premarket Notification 510(k)
Section 12 – Drawings of Proposed Device**

VitalHeat™

12.3 Block Diagrams

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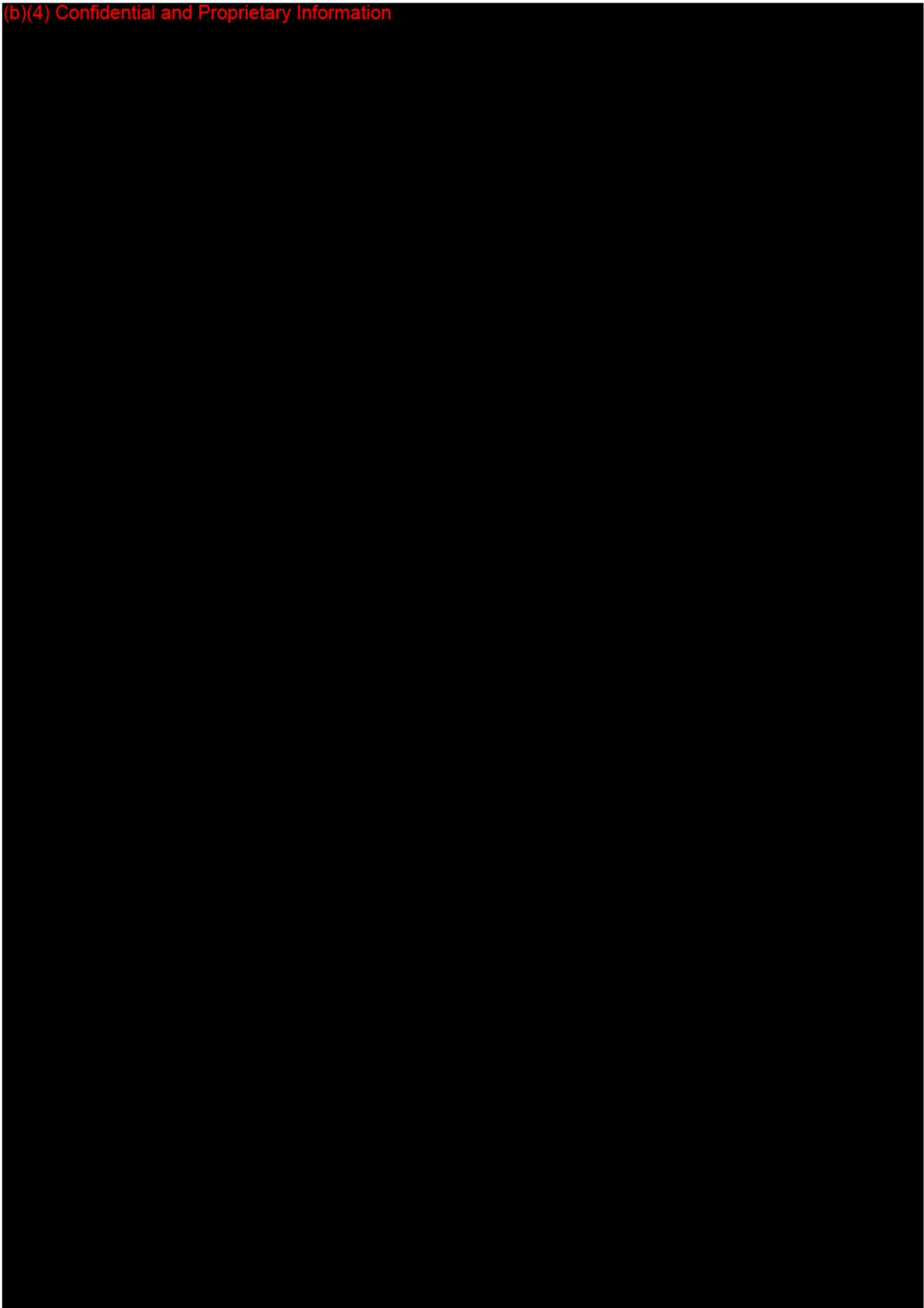
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Dynatherm Medical Inc.

2/16/2004

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3

Dynatherm Medical Inc.

2/16/2004

285

(b)(4) Confidential and Proprietary Information

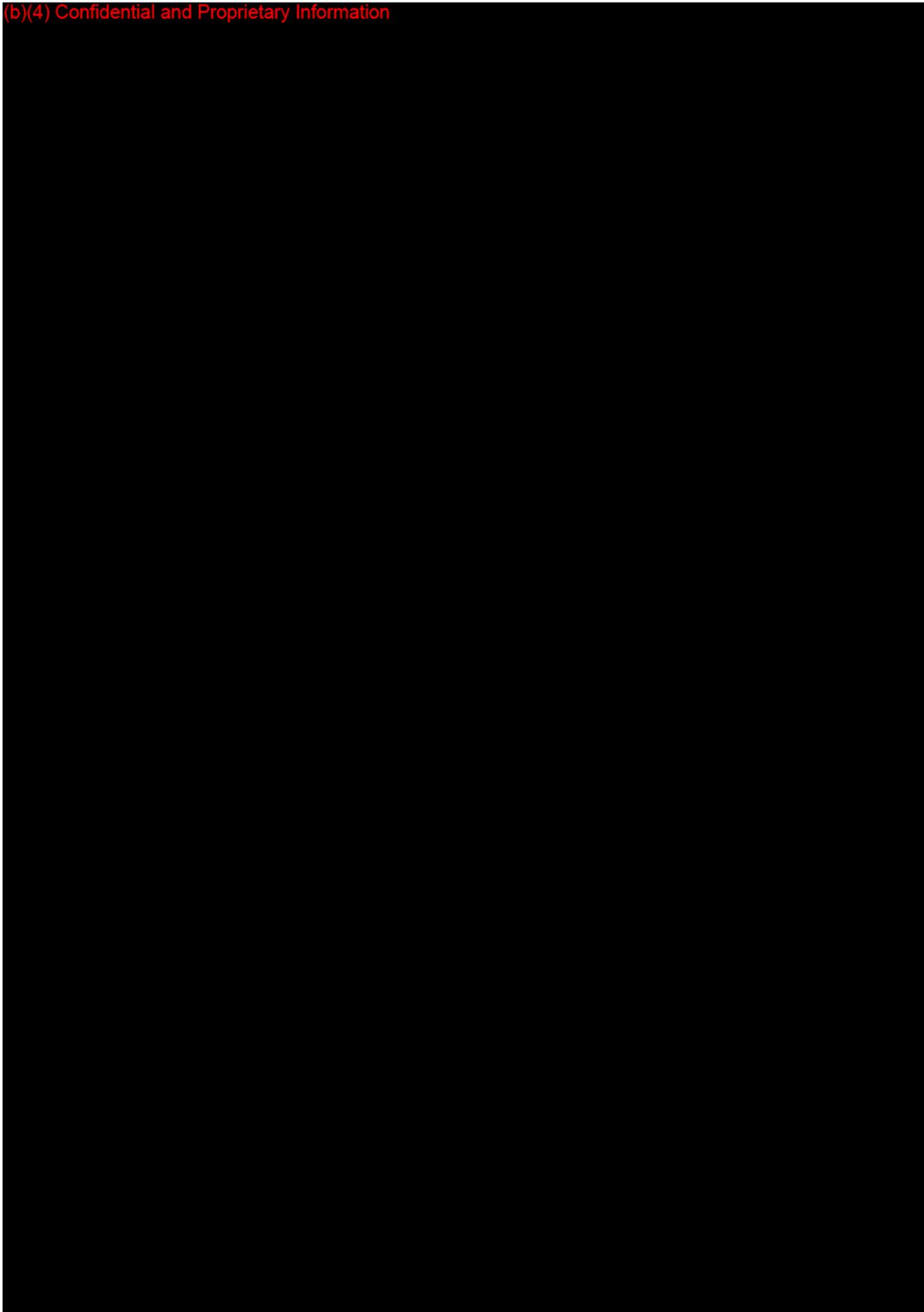


Dynatherm Medical Inc.

2/16/2004

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Dynatherm Medical Inc.

2/16/2004

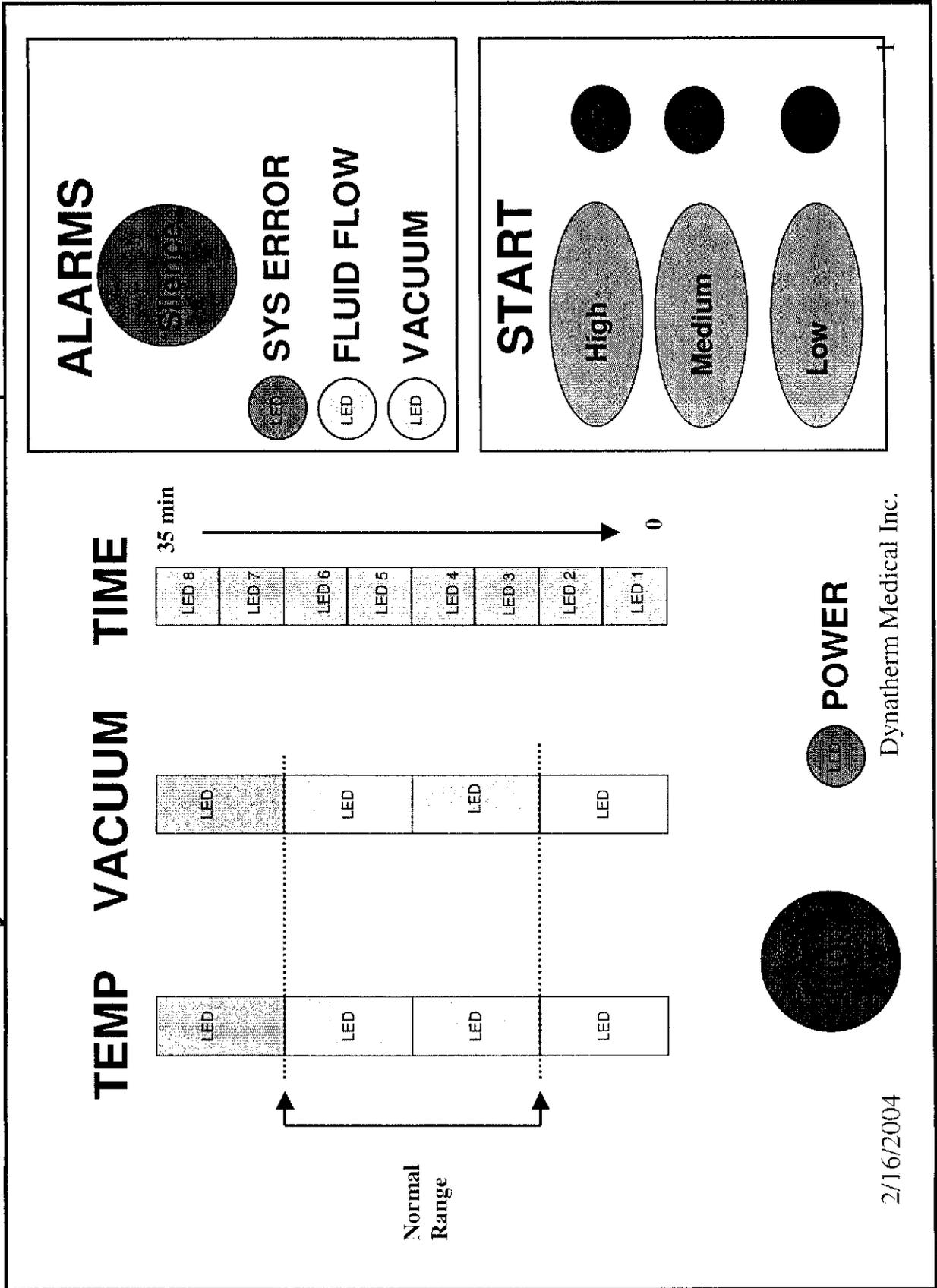
287

**Premarket Notification 510(k)
Section 12 – Drawings of Proposed Device**

VitalHeat™

12.4 Front Panel

Dynatherm Controller front panel



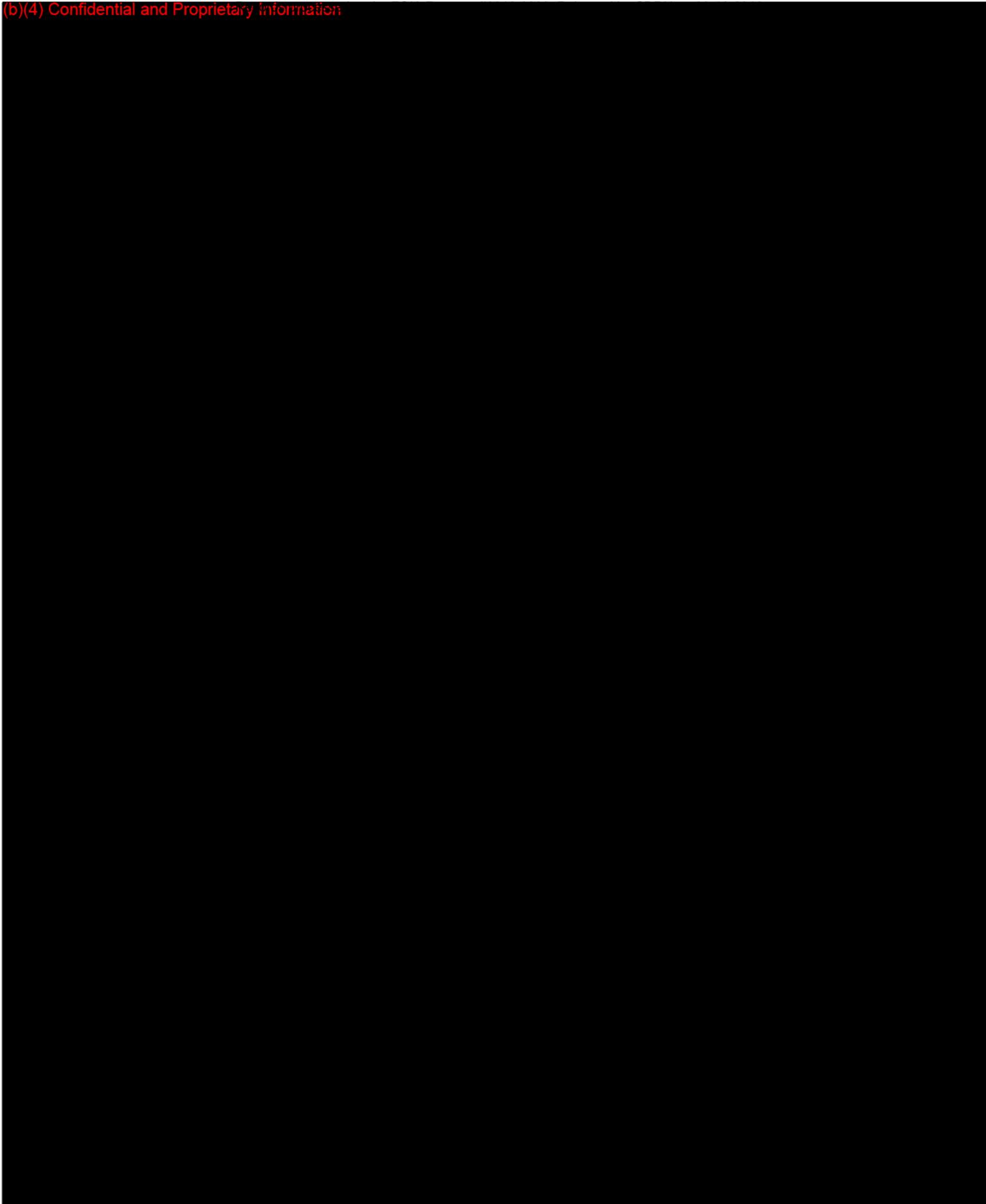
Dynatherm Medical Inc.

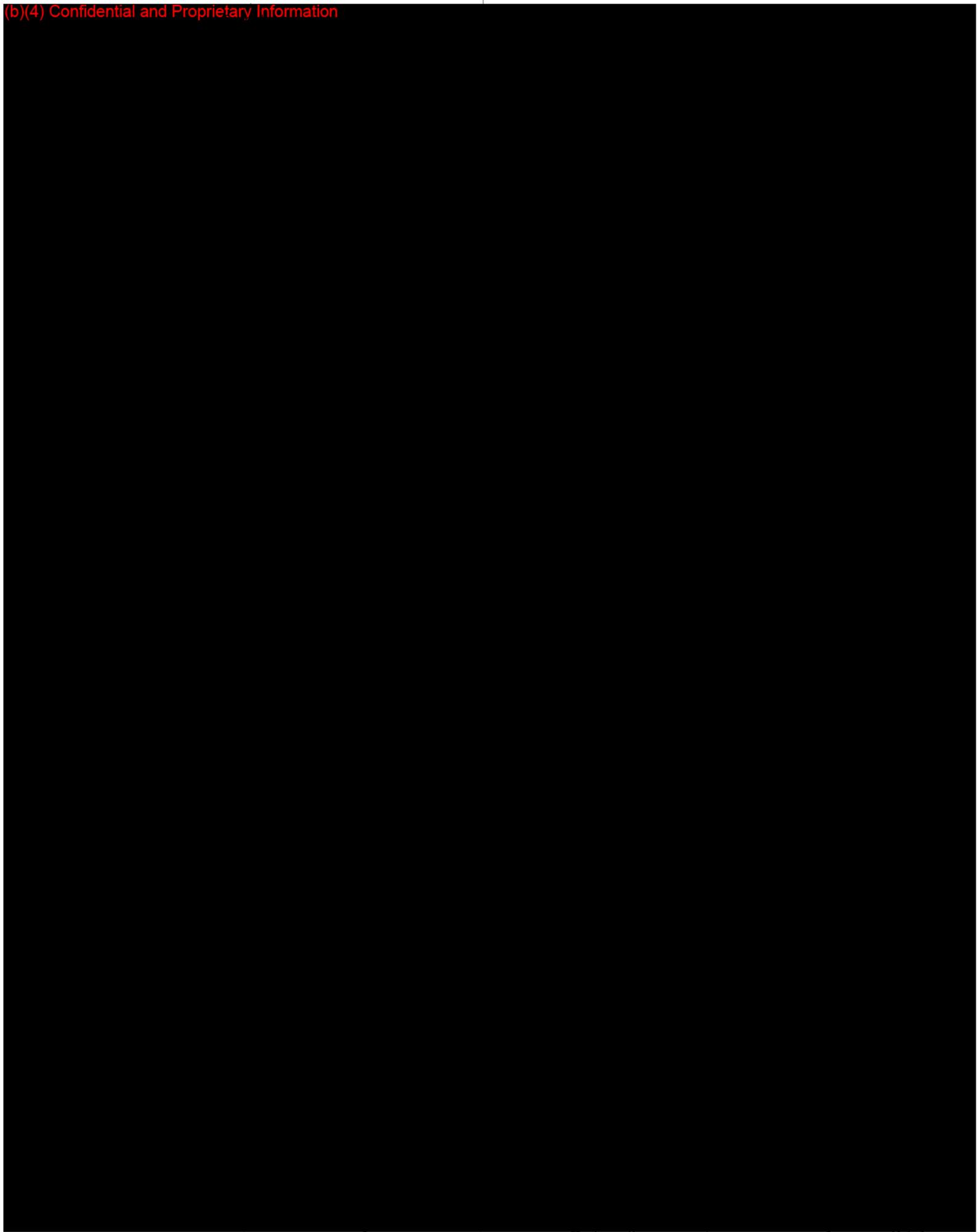
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**Premarket Notification 510(k)
Section 12 – Drawings of Proposed Device**

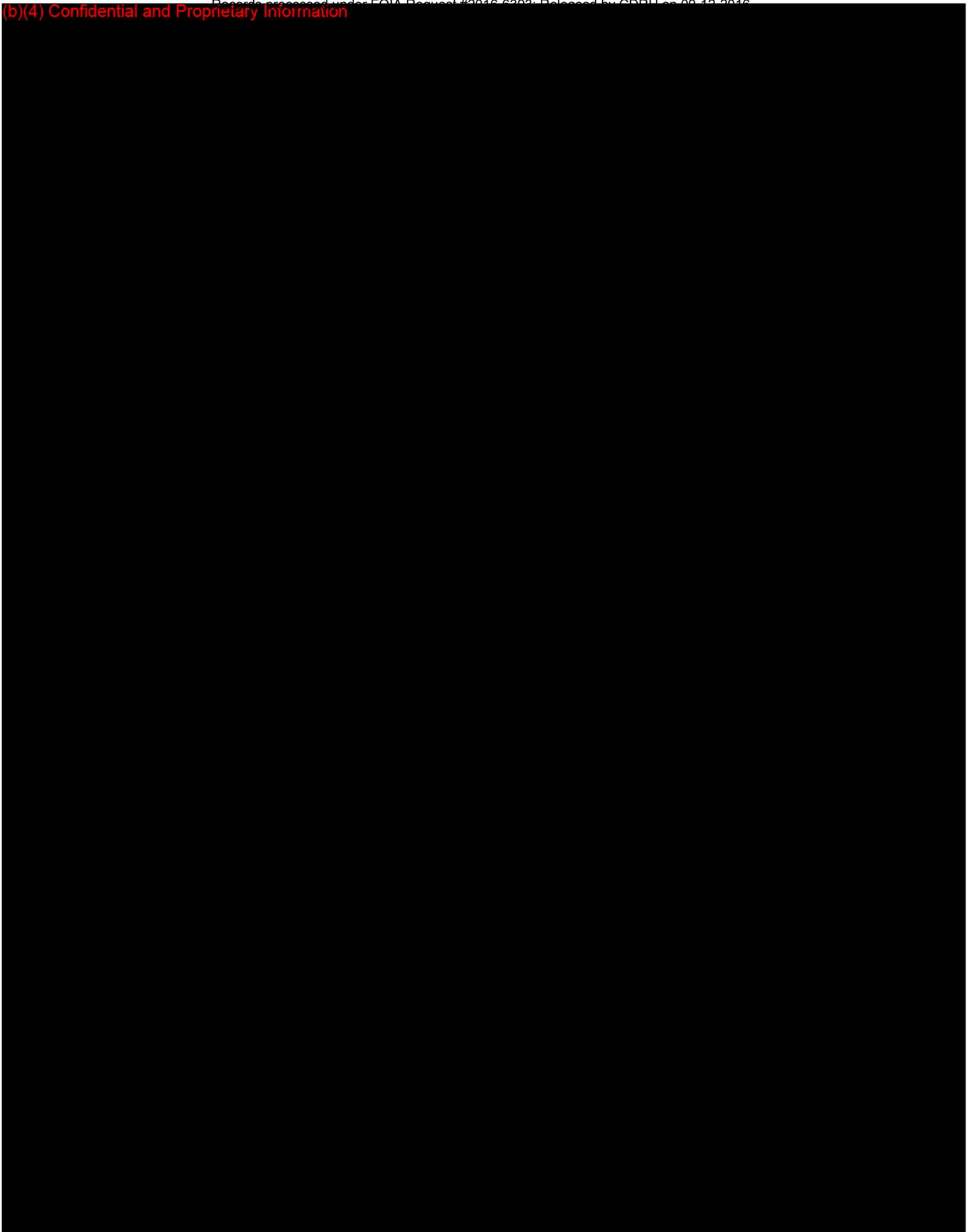
VitalHeat™

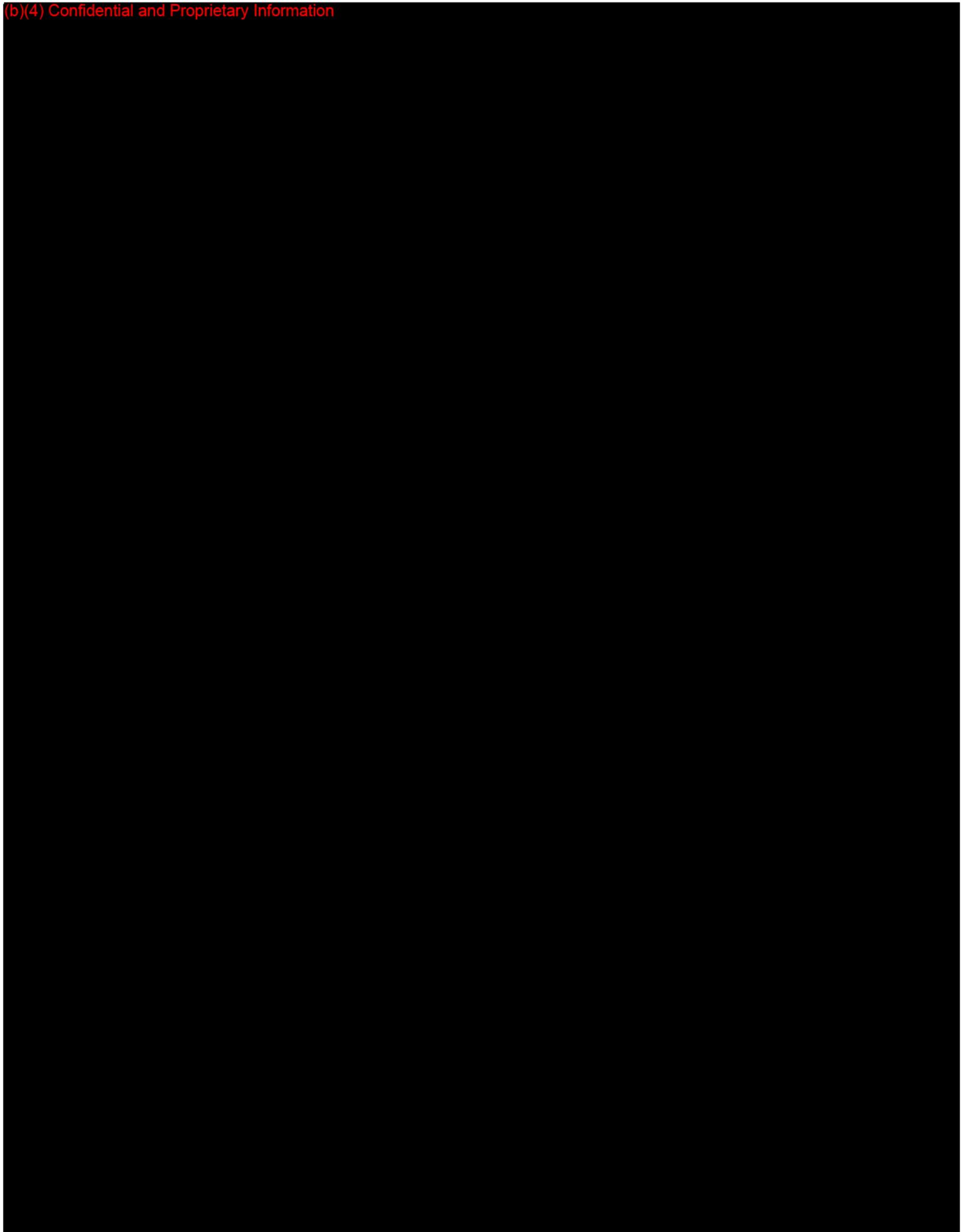
12.5	Water Tank Assembly
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(b)(4) Confidential and Proprietary Information



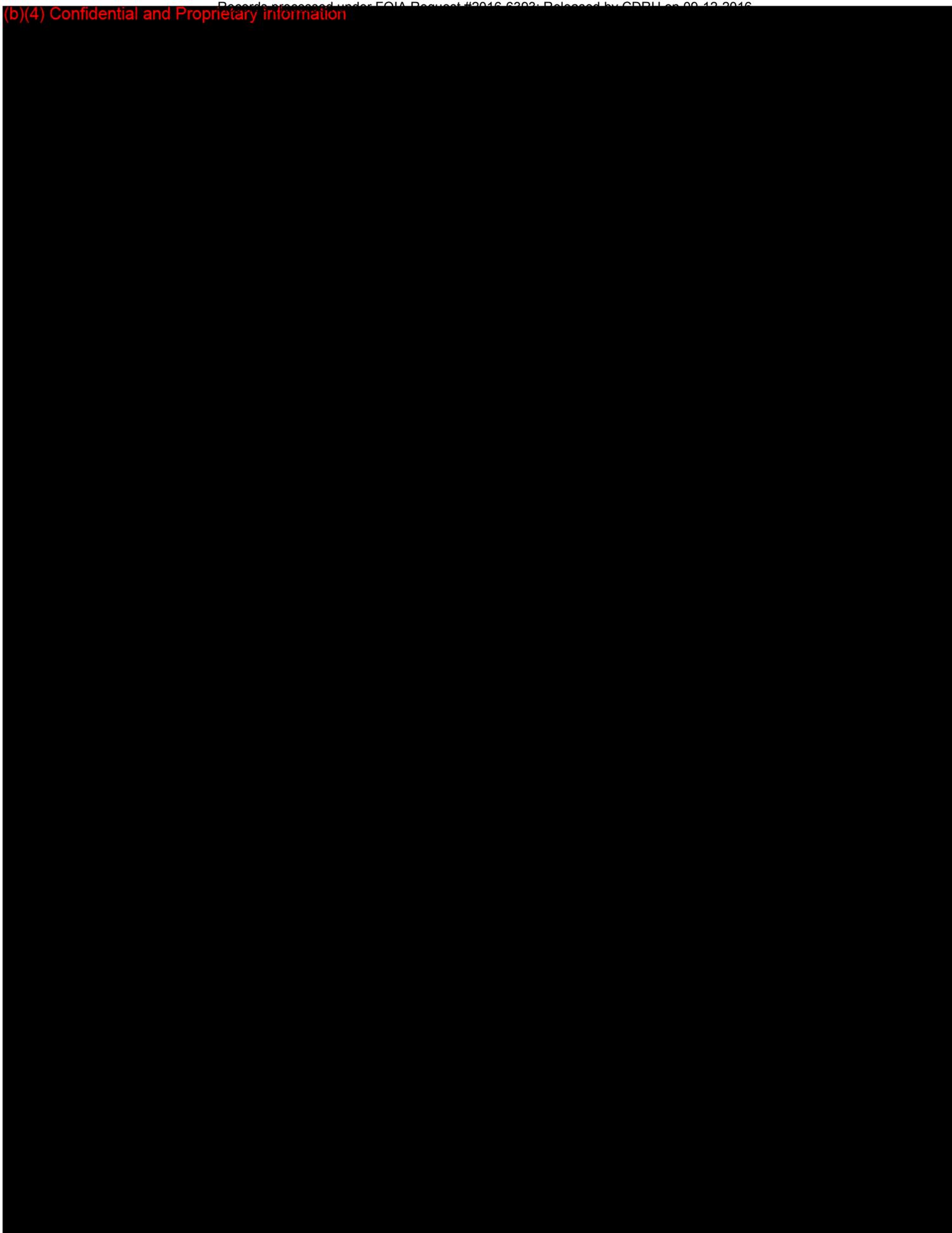


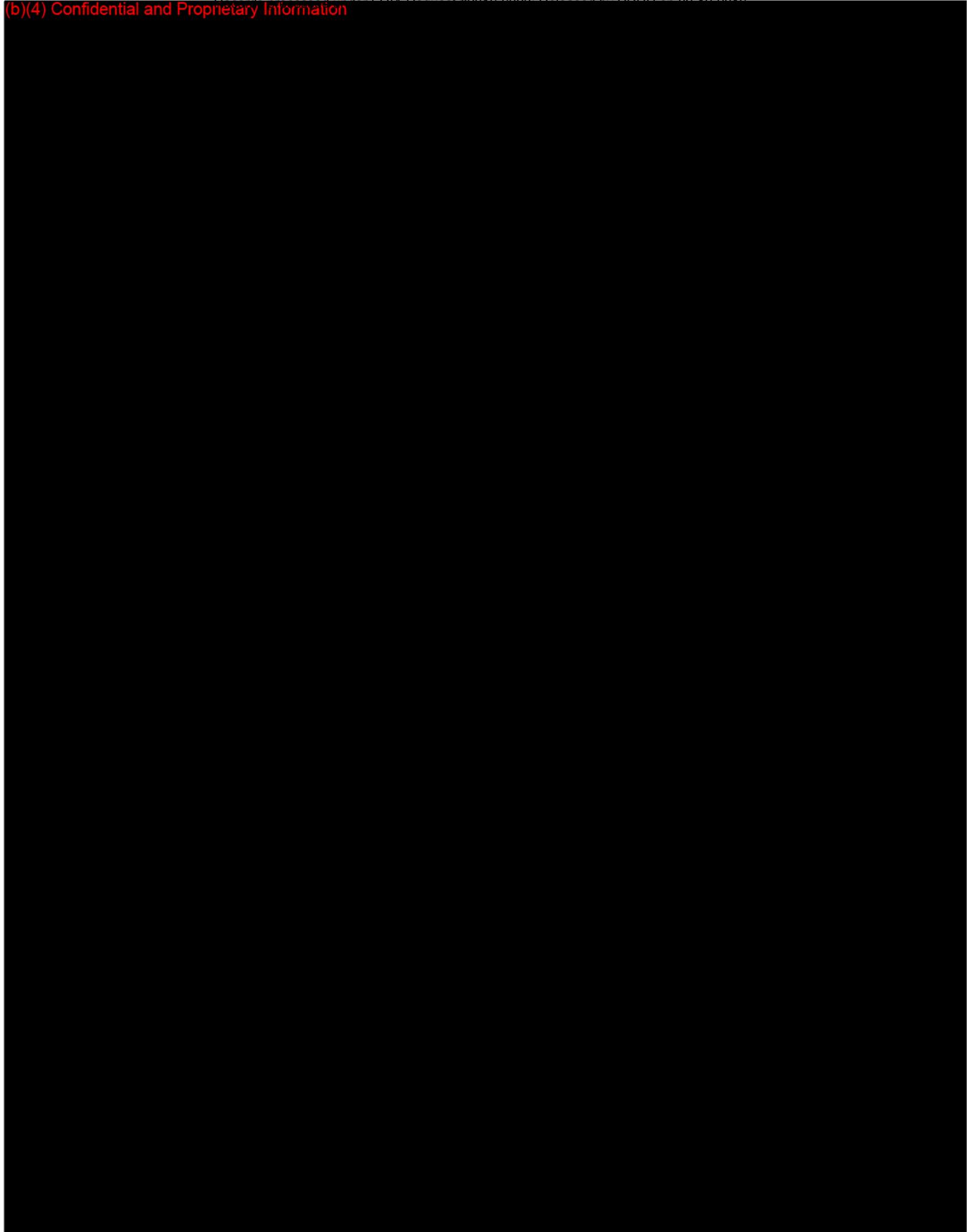
**Premarket Notification 510(k)
Section 12 – Drawings of Proposed Device**

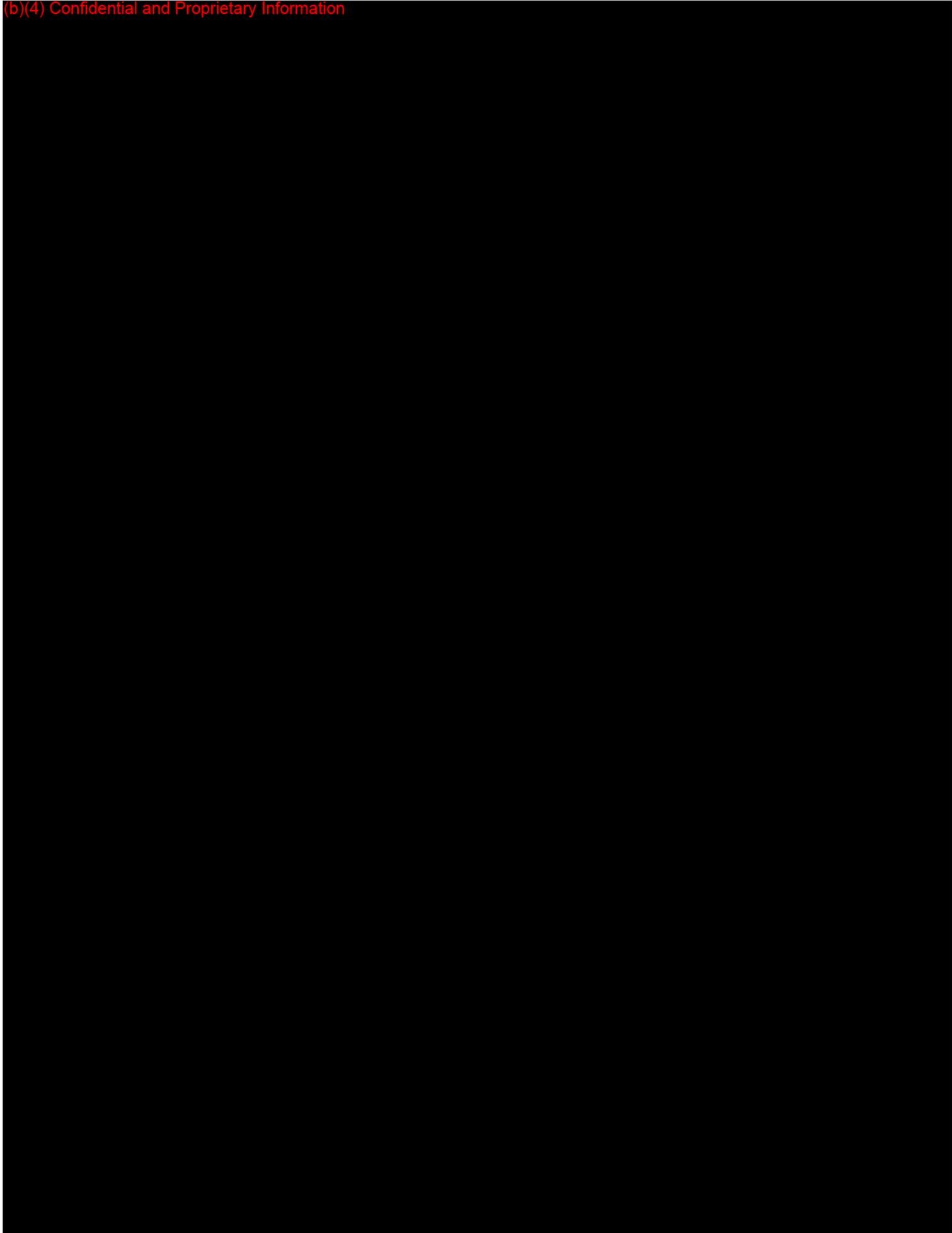
VitalHeat™

12.6 Controller Sub Assembly

(b)(4) Confidential and Proprietary information





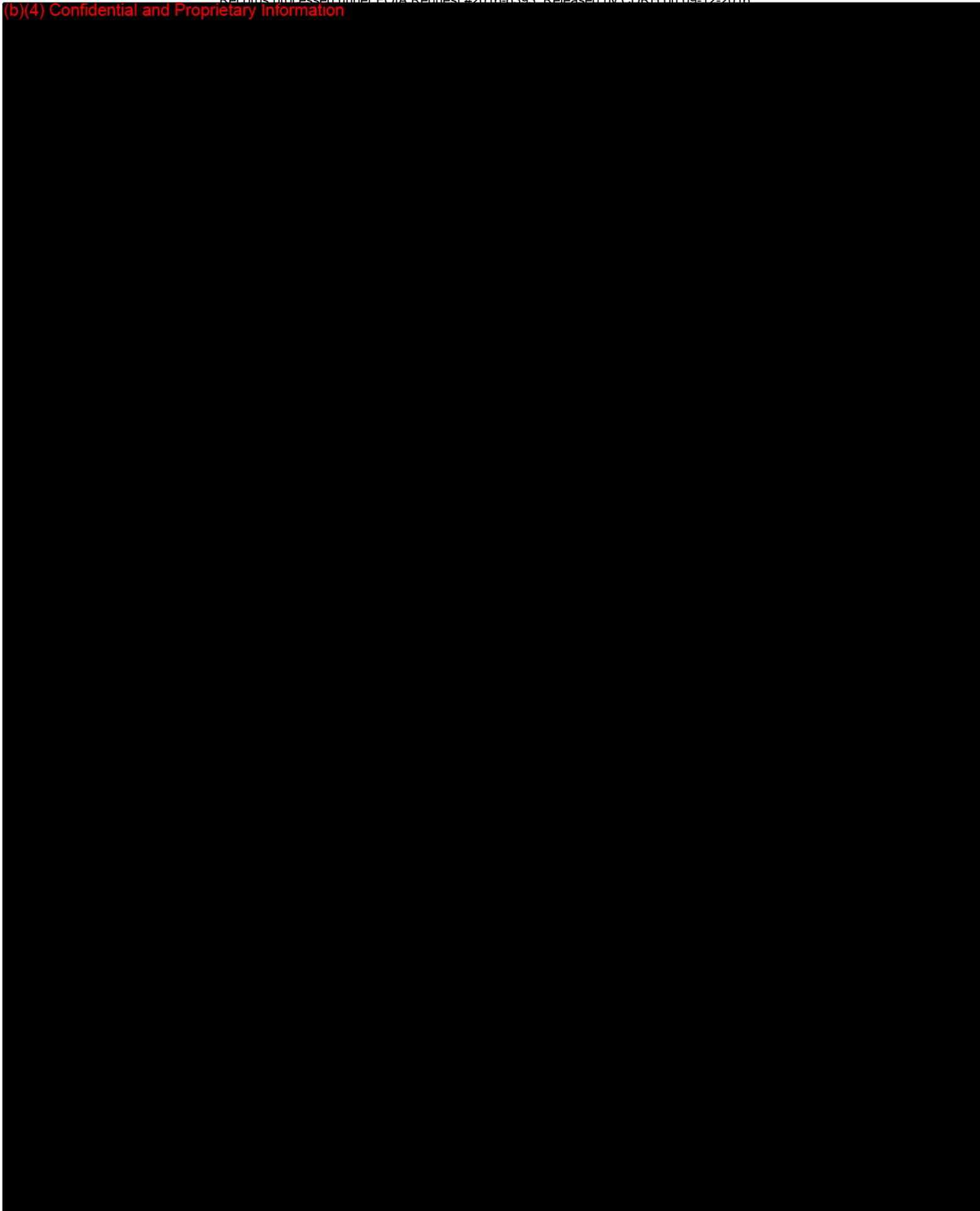


**Premarket Notification 510(k)
Section 12 – Drawings of Proposed Device**

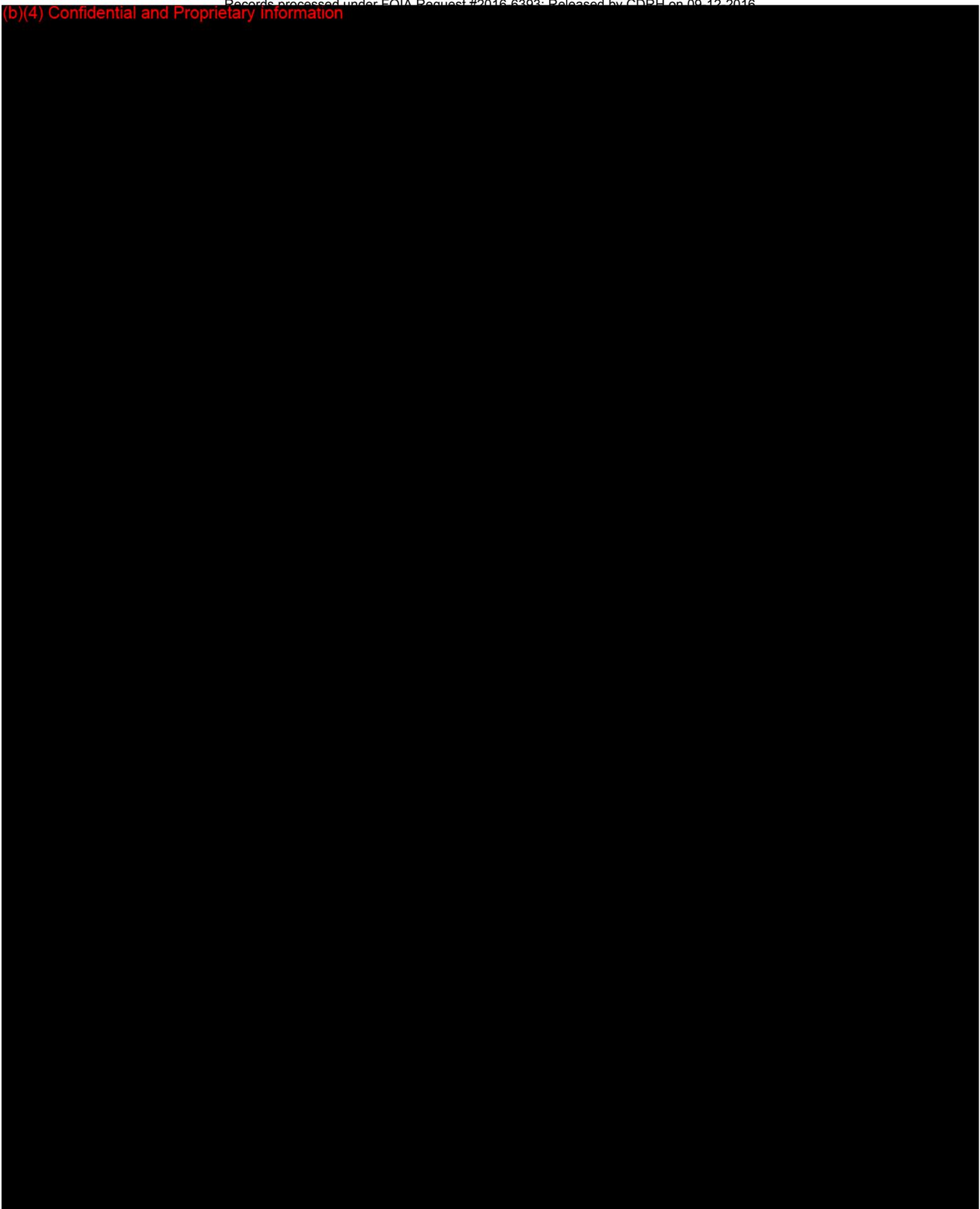
VitalHeat™

12.7 Paddel Sub Assembly

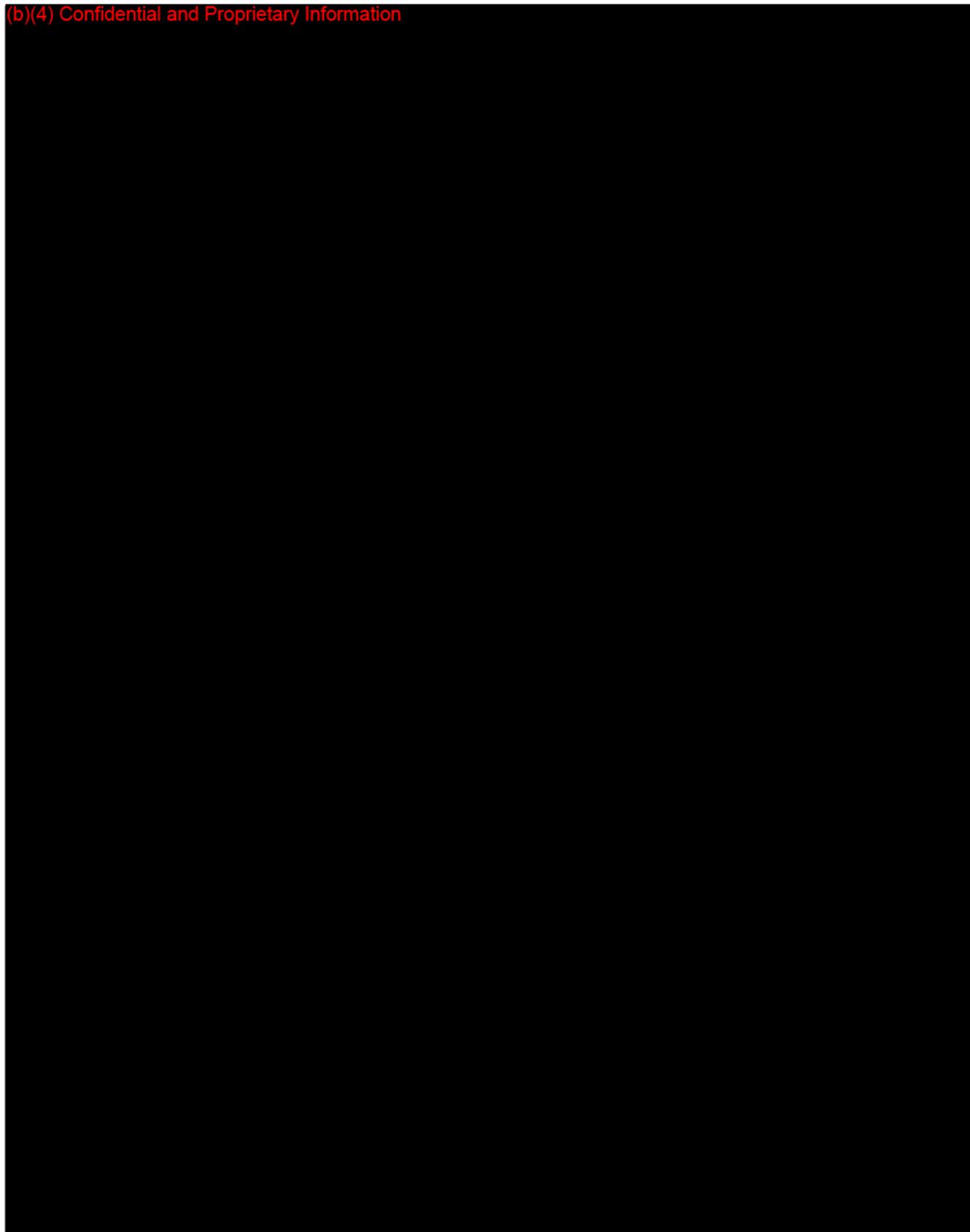
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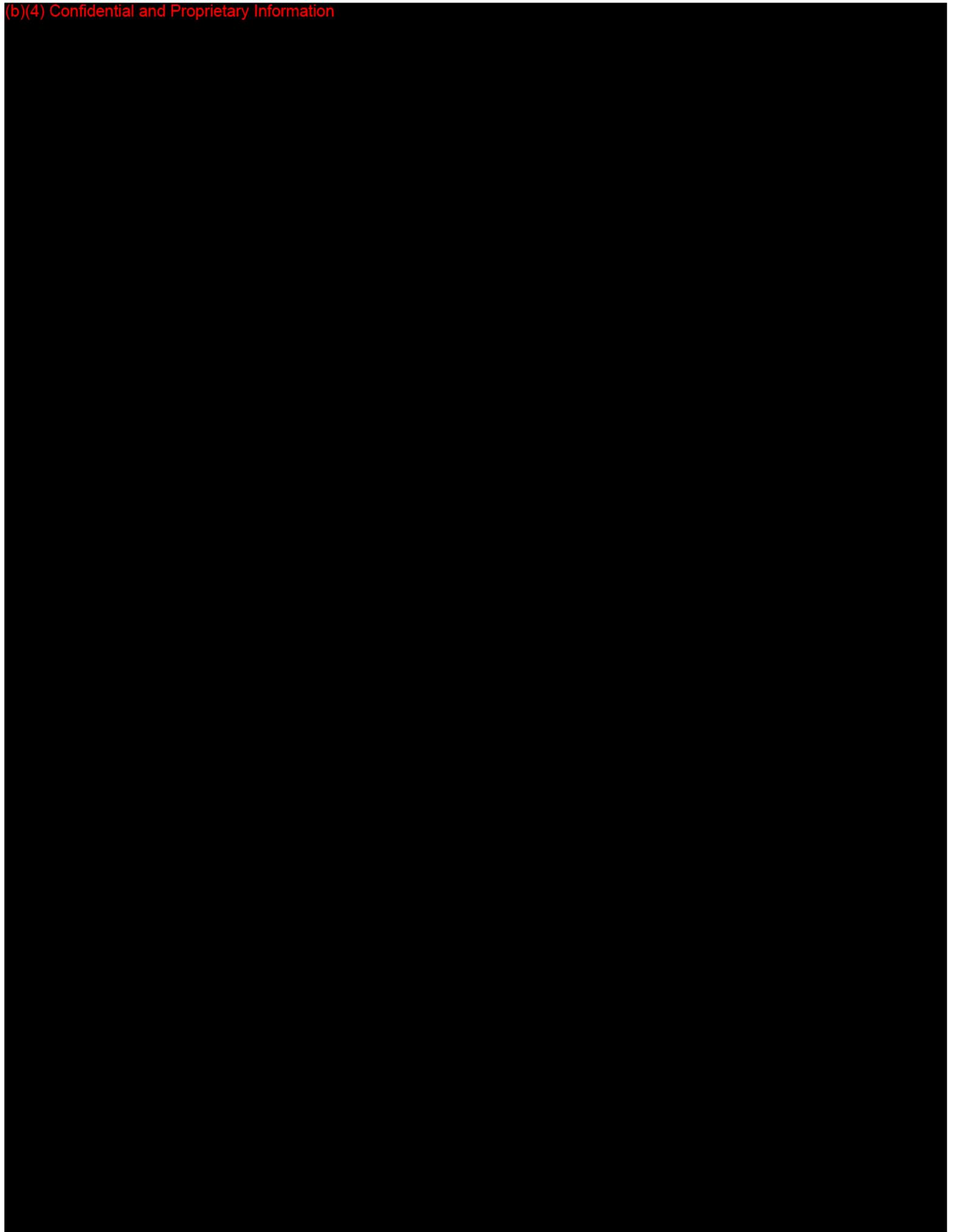


(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

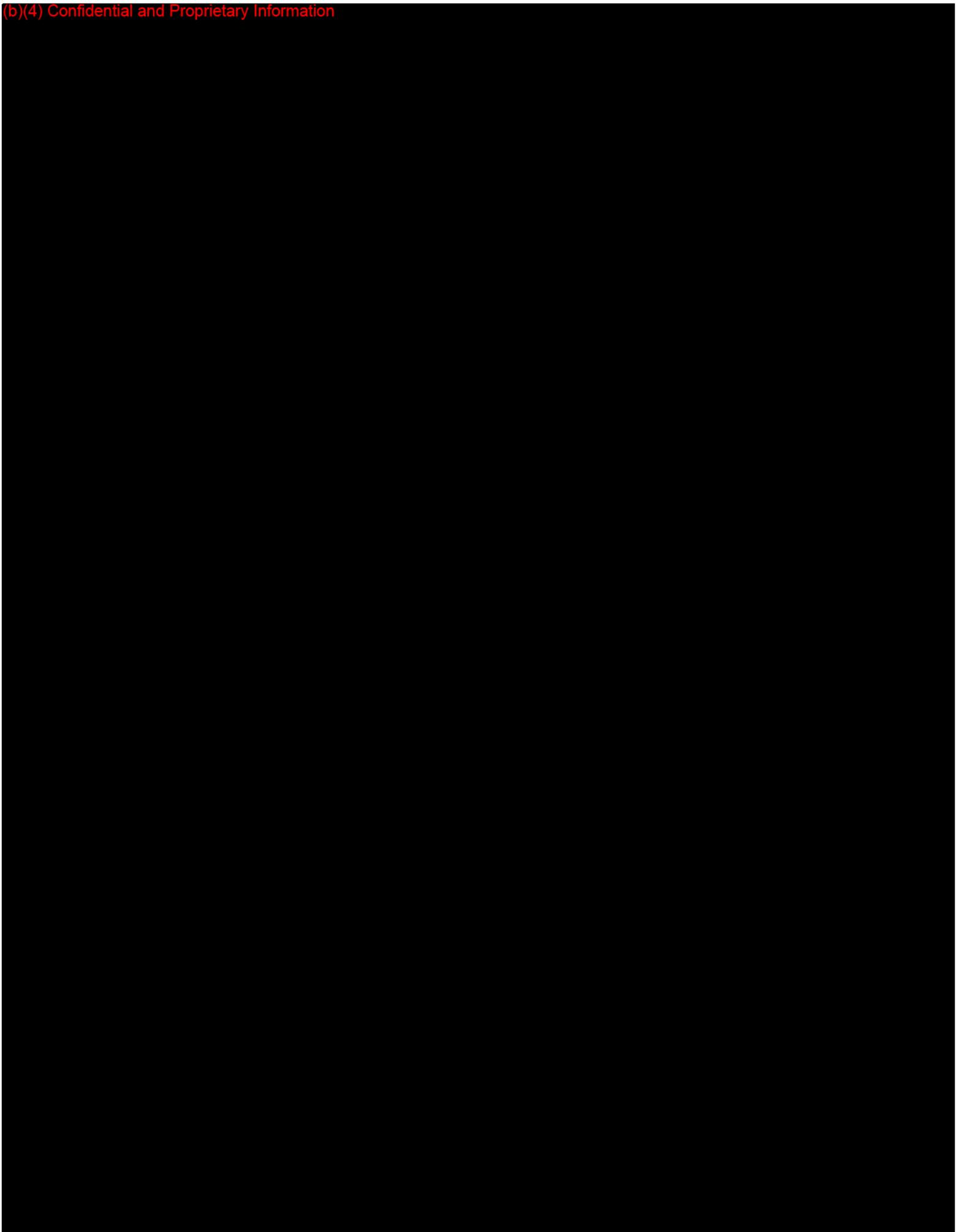


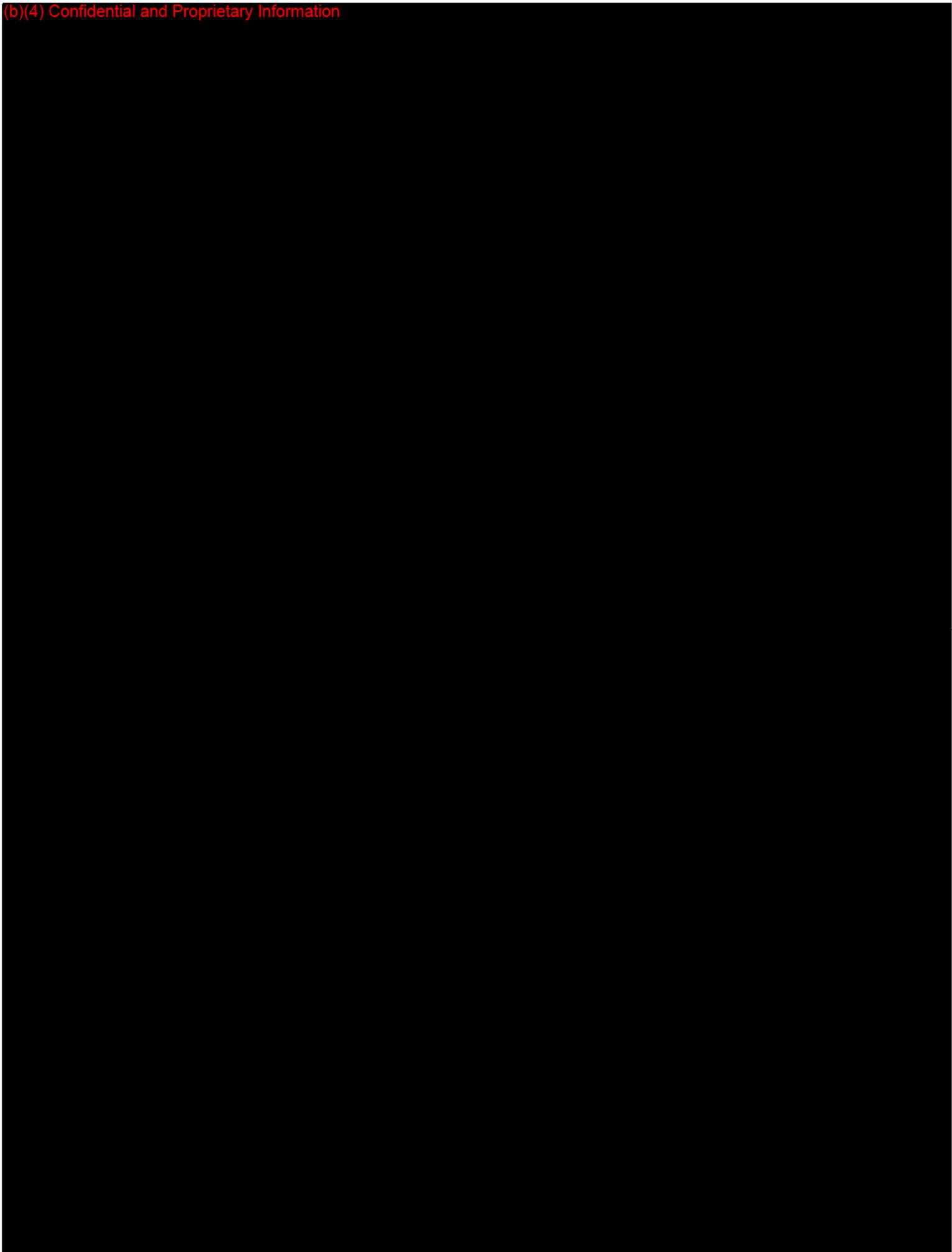


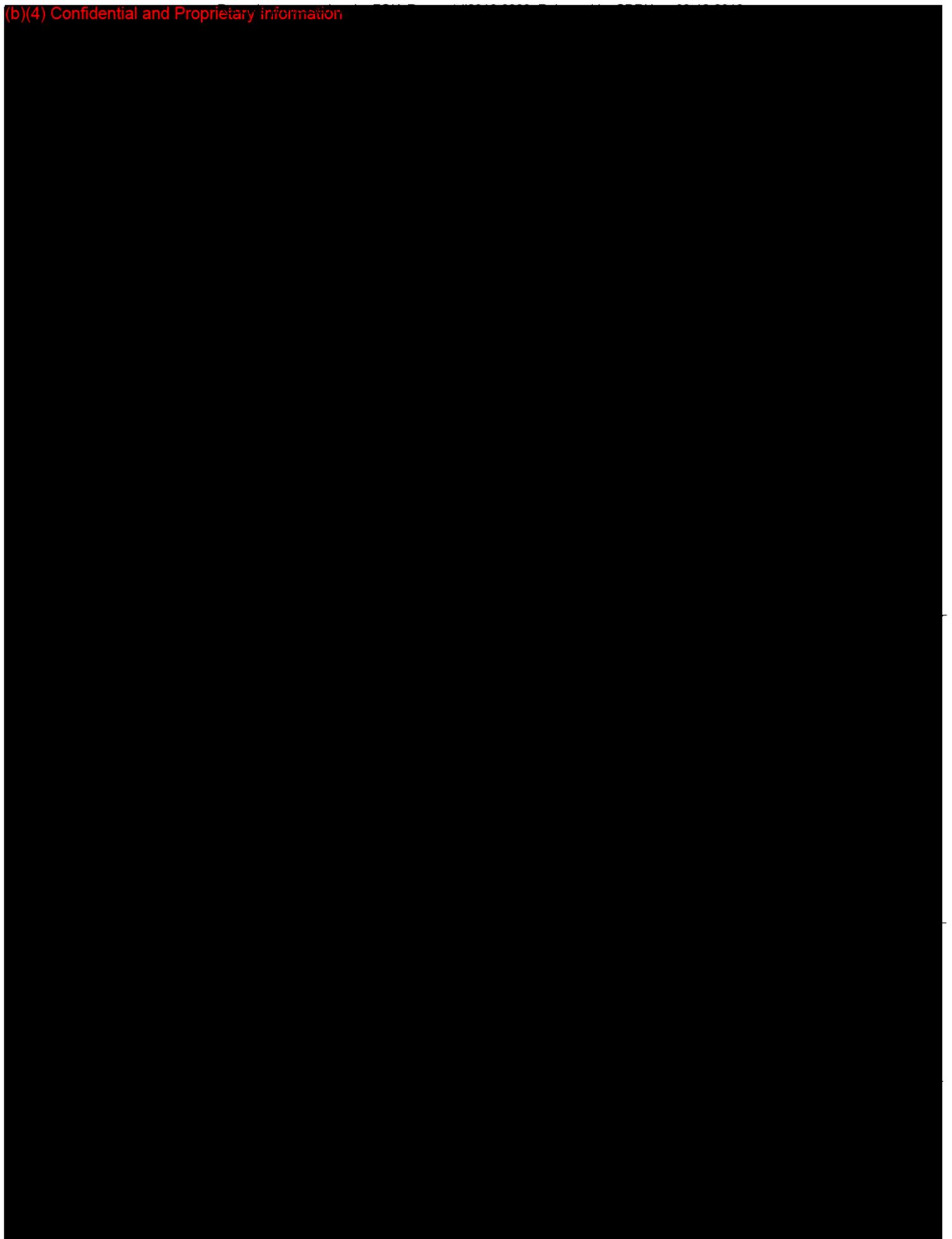
(b)(4) Confidential and Proprietary Information



305





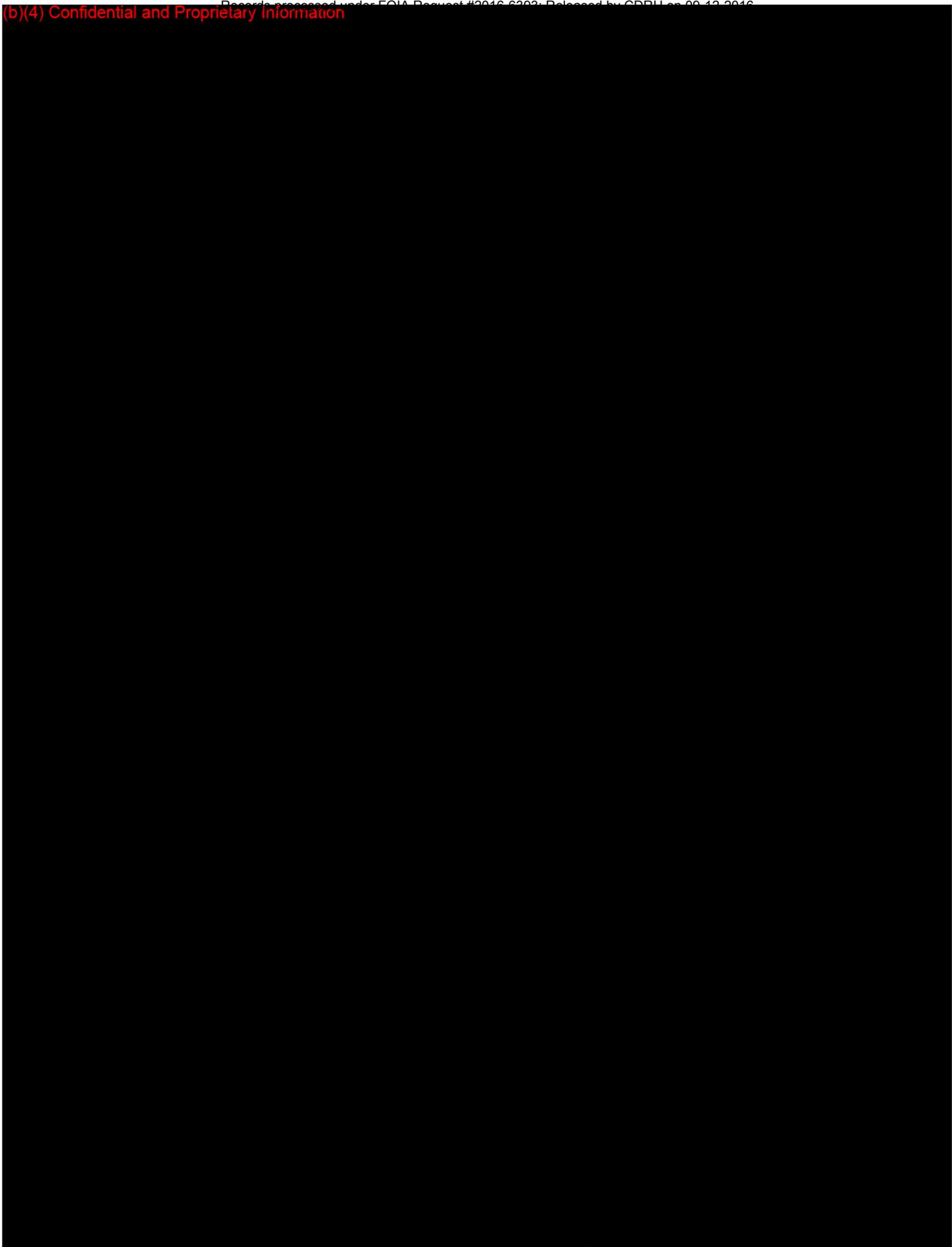


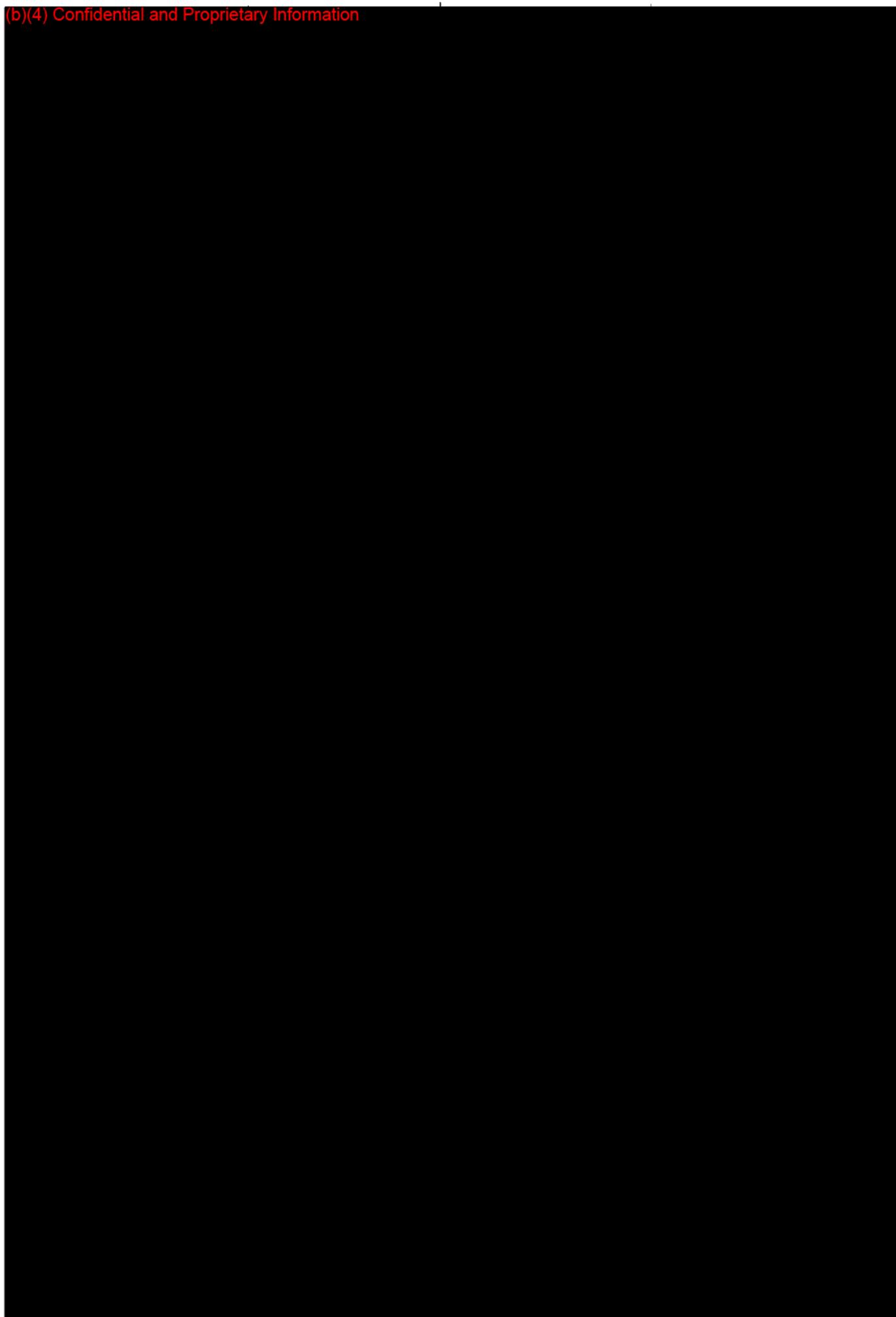
**Premarket Notification 510(k)
Section 12 – Drawings of Proposed Device**

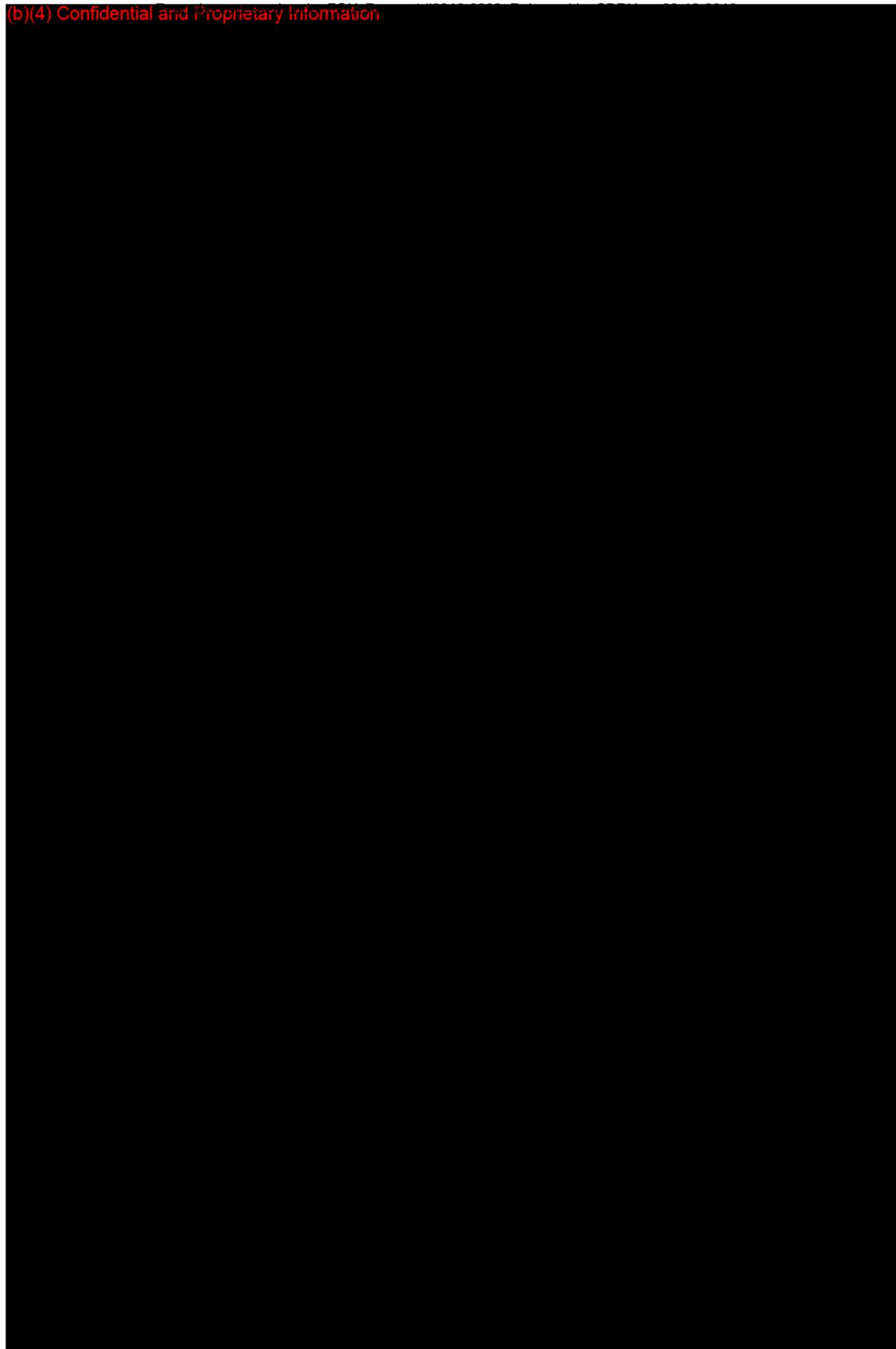
VitalHeat™

12.8	Mitt Assembly
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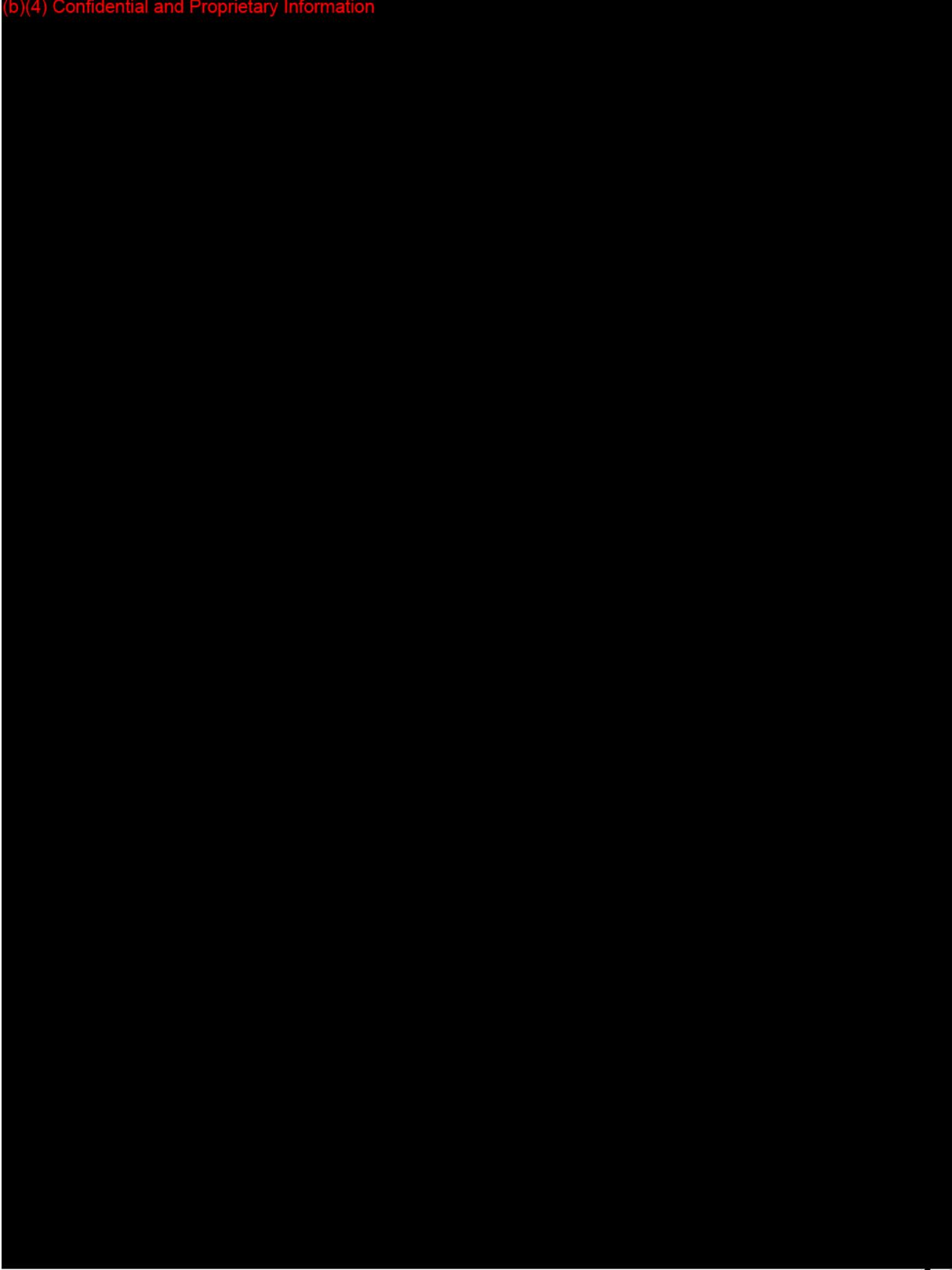
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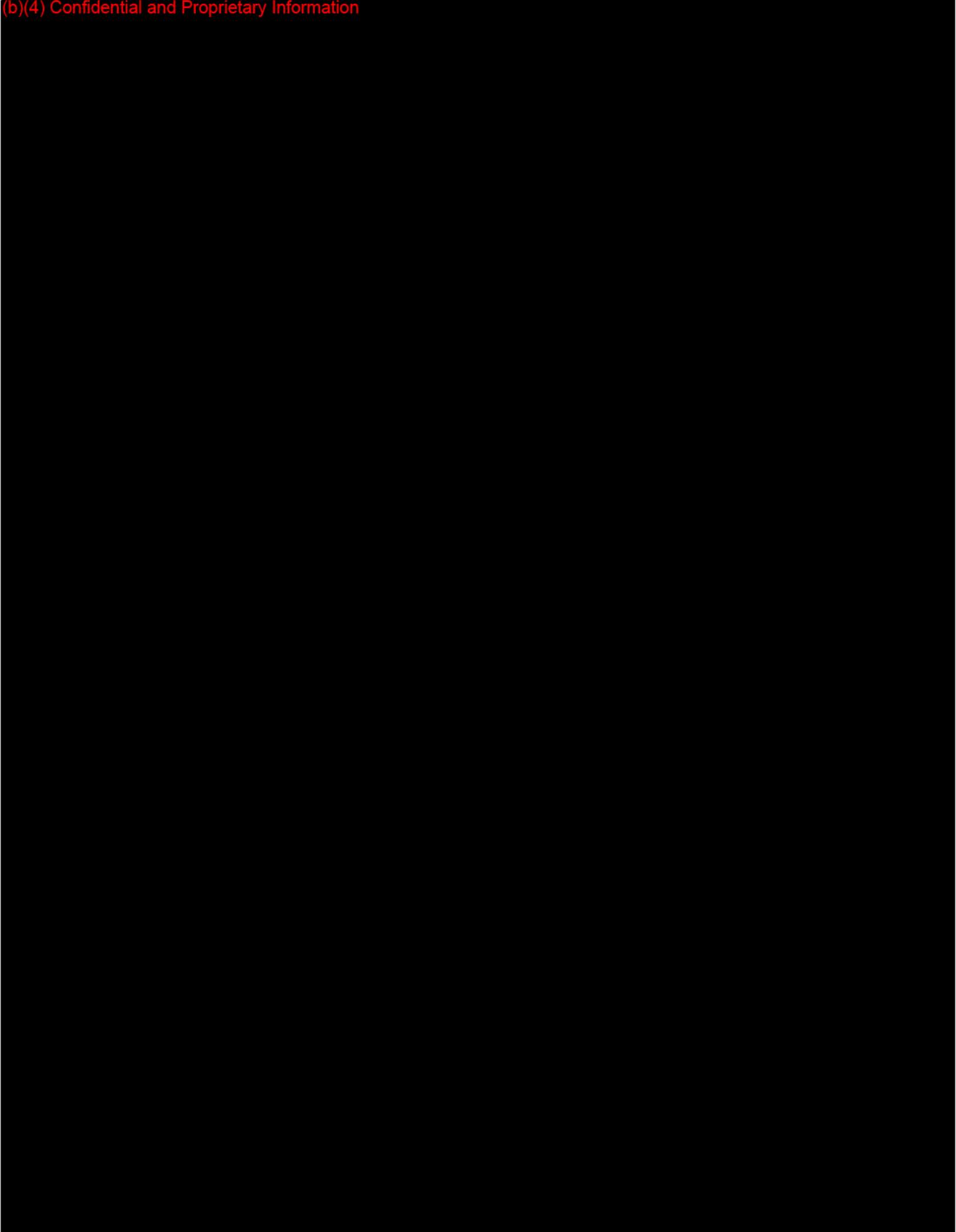




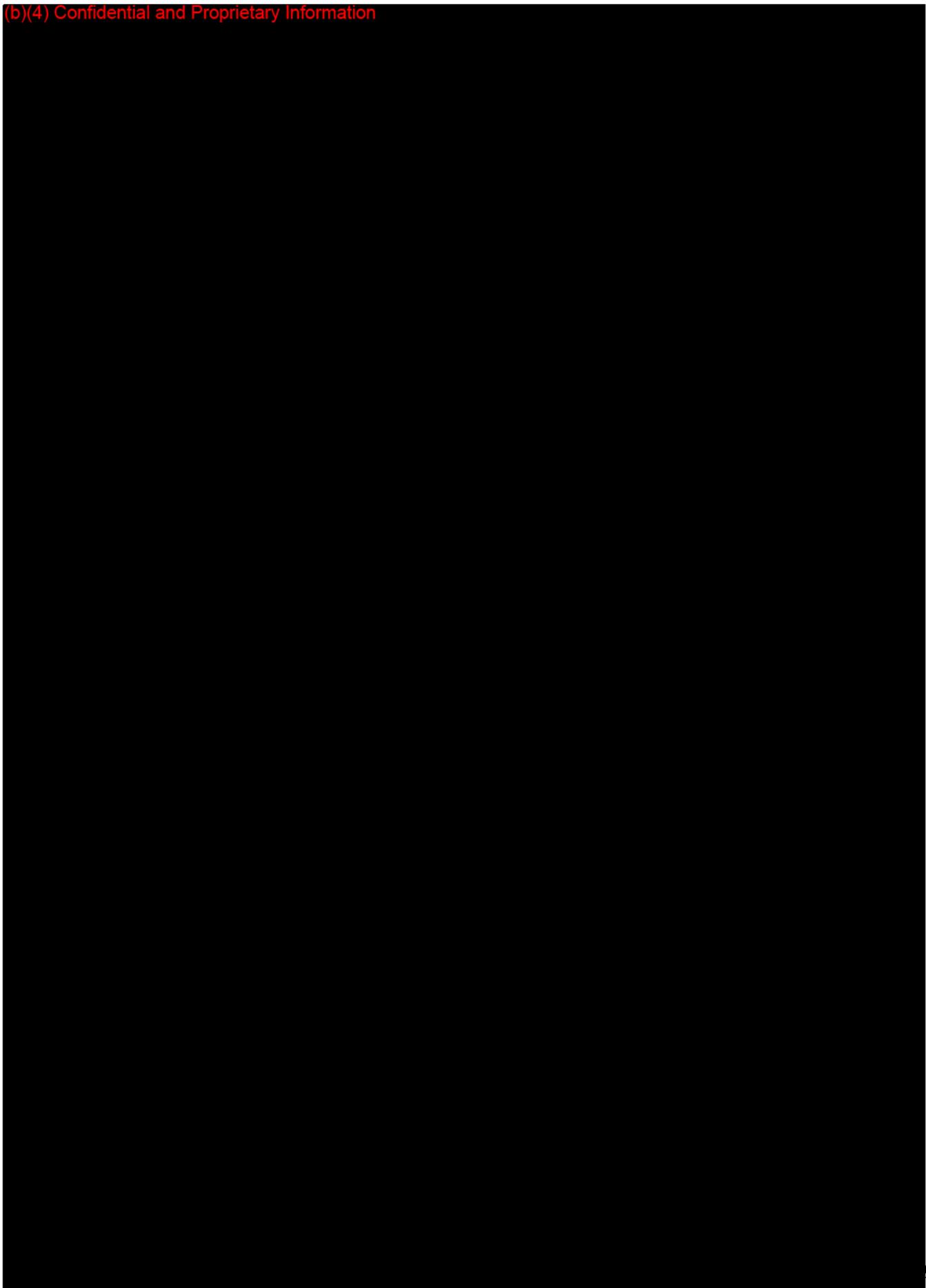
(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

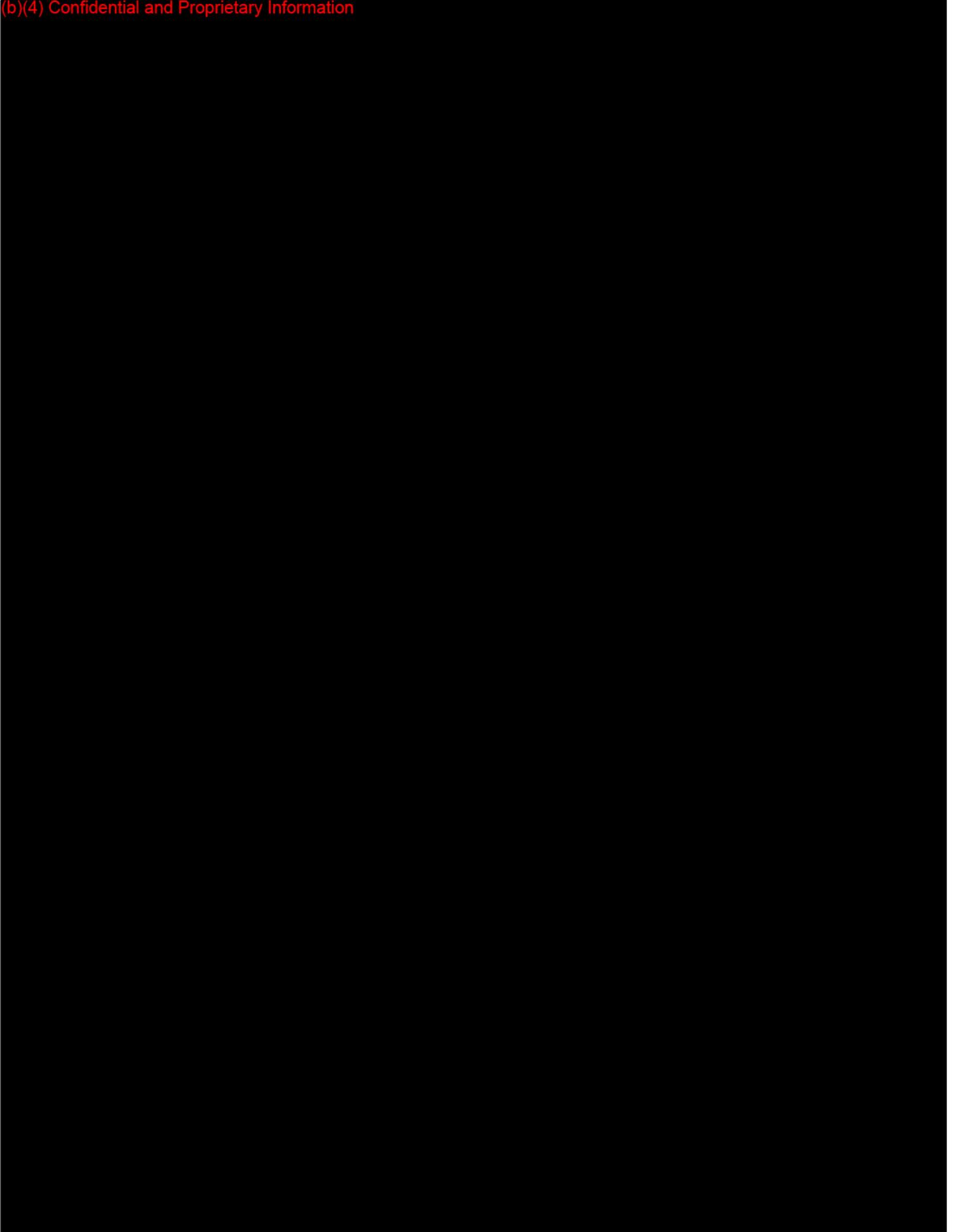


(b)(4) Confidential and Proprietary Information



15

(b)(4) Confidential and Proprietary Information



Premarket Notification 510(k)
Section 13 – Design and Performance Criteria and Testing

VitalHeat™

13.1 VitalHeat™ Product Specification

13.2 VitalHeat™ Test Plan

13.3 Test Report

317

**Premarket Notification 510(k)
Section 14 – Risk Analysis**

VitalHeat™

14.1 Hospital VitalHeat™ Risk Analysis

14.2 Failure Analysis for 510-2001 VitalHeat™ Analog Controller

14.3 Risk Analysis Data

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**Premarket Notification 510(k)
Section 14 – Risk Analysis**

VitalHeat™

14.1 Hospital VitalHeat™ Risk Analysis

354

**Premarket Notification 510(k)
Section 15 – Aquarius Thermo-STAT- K970367**

VitalHeat™

15.0 Aquarius Thermo-STAT – K970367
--

365

DEC 17 1997

510(K) SUMMARY

TRADE NAME:

Thermo-STAT System

GENERIC NAME:

Body Core Thermoregulation System

CLASSIFICATION OF PERFORMANCE STANDARD:

The Food and Drug Administration has classified devices of this generic type into Class II, DWJ. To date, no performance standards have been established for devices of this type.

INTENDED USE:

The Thermo-STAT is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and a thermal load (heat) to a distal appendage.

DEVICE DESCRIPTION:

The Thermo-STAT is a non-invasive and portable body core warming device which provides a non-invasive technique to treat and prevent hypothermia. The Thermo-STAT's principle of action for counteracting hypothermia is to create a thermal pipeline between the skin and the body core. The Thermo-STAT functions by applying a combination of heat and pressure to only the distal aspect of an arm or leg. Using the Thermo-STAT, a thermal load is exchanged between the application site and the body core. Vasoconstriction in a hypothermic individual prevents superficial heat alone from effectively altering the body core temperature. The Thermo-STAT circumvents this "vasoconstrictive blockade" with a slight negative pressure (40-60mmHg) and enables a thermal load to be transferred directly and exclusively from a thermal heat pad to the body core via the bloodstream. Current means, such as forced air rewarming, fail to effectively overcome the "vasoconstrictive blockade."

PERFORMANCE DATA:

Sample devices were subjected to physical bench testing. Tests included current vacuum and heat cycle test, flow rate capabilities, and performance under simulated conditions. Based on these test results, it was concluded that the design and proper fabrication of that design offered a considerable safety margin with regard to simulated clinical use.

HUMAN CLINICAL EVALUATION:

A clinical study was performed under a non-significant risk IDE to test and confirm the system's functionality and safety during non-invasive active rewarming of the body core temperature for hypothermic patients. A clinical evaluation was randomly performed on 22 patients undergoing a variety of general surgical procedures. These patients were observed hypothermic at the conclusion of their surgery and, therefore, the Thermo-STAT was employed to raise their body core temperature. The combination of negative pressure and thermal load was non-invasively applied to hypothermic patients' distal limb with their informed consent. A 2°C rise in body core temperature was observed in the first 10 minutes of application of the Thermo-STAT device. It was observed that there were no side effects to the patient from this treatment. The clinical tests resulted in the conclusion that negative pressure rewarming is a viable technique for rapidly rewarming patients in the PACU.

BIOCOMPATIBILITY TESTS OF MATERIALS:

Tests for biocompatibility of materials used in the fabrication of the Thermo-STAT were performed to establish that the materials used in the device meet the qualifications for short-term use non-invasively on the skin's surface. As a result of these tests, it was concluded that the materials met the qualifications for short term use non-invasively on the skin's surface.

STERILIZATION:

The Thermo-STAT is designed to be a non-sterile product.

PACKAGING:

The Thermo-STAT (seal and thermal fluid pad) is for single-use only and will be placed in a protective dispenser. A protective overshipper will be utilized for shipping.

Packaging was designed to protect the device from damage during processing, storage and distribution.

SUBSTANTIAL EQUIVALENCE:

The Thermo-STAT is equivalent in its intended use, as well as design, composition and function, to the rewarming devices legally marketed by Augustine Medical, MityVac and Prism Technologies.



Mr. W. Jeffrey Chandler
President and CEO
Aquarius Medical Corporation
16099 North 82nd Street
Suite B-1
Scottsdale, AZ 85260

DEC 17 1997

Re: K970367
Thermo-STAT™ System
Regulatory Class: II (Two)
Product Code: DWJ
Dated: September 26, 1997
Received: September 26, 1997

Dear Mr. Chandler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. W. Jeffrey Chandler

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

369 15-2

510(k) Number (if known): K 970367

Device Name: Thermo-STAT™ System

Indication for Use: The Thermo-STAT is designed to non-invasively treat hypothermic patient rewarming their body core. This is accomplished with local application of neg pressure and a thermal load (heat) to a distal appendage.

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

Concurrence of DCRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K 970367

Prescription Use
(Per 21 CFR 801.109)

OR

Over the Counter Use

15-3

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Premarket Notification 510(k)
Section 16 – Acrotherm – K003368

VitalHeat™

16.0	Acrotherm – K003368
------	---------------------

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K003368

JAN 1 9 2001

AcroTherm

Premarket Notification 510(k)
Section 2-Certifications and Summaries

Aquarius Medical Corporation

16047 North 82nd Street

Scottsdale, Arizona 85260

Non-Confidential Summary of Safety and Effectiveness

Page 1 of 3
27-Oct-00

Aquarius Medical Corporation, Inc. Tel - (480) 991-1818
16047 North 82nd Street
Scottsdale, Arizona 85260 Fax - (480) 991-4335

Official Contact: Michael McCauley, President
Proprietary or Trade Name: AcroTherm
Common/Usual Name: AcroTherm
Classification Name: Thermal Regulating System
Device: AcroTherm
Predicate Devices: Aquarius Medical Corporation, Inc.
Thermo-STAT - K970367
MTRE Advanced Technology, Inc.
Allon 2001 - K001546

Device Description:

The Aquarius Medical Corporation's AcroTherm consists of the following elements:

- Warming chamber with tubing set
- Control Unit
- Tubing Set
- Disposable Arm Liner

The AcroTherm is a compact, portable thermal warming device for use in health care facilities to help patients recover from the discomfort and consequences of lowered core temperature. The device utilizes a technology, which combines sub-atmospheric pressure (SAP) and a heating element on one heat exchanging extremity. (The current design is to be utilized on a hand and forearm.) The combination of sub-atmospheric pressure and a heating element allow for the maximum transfer of heat through the heat exchange vasculature. The compact design allows for minimum coverage of the patient (hand & forearm), which should not impede standard patient care and/or full body access.

Indicated Use:

The AcroTherm is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

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Premarket Notification 510(k)

AcroTherm

Section 2-Certifications and Summaries

Aquarius Medical Corporation

16047 North 82nd Street

Scottsdale, Arizona 85260

Non-Confidential Summary of Safety and Effectiveness

Page 2 of 3
27-Oct-00

Patient Population:

The system is for use with patients experiencing cold who are 18 years of age and older.

Environments of Use:

The device is intended for use throughout healthcare facilities.

Contraindications:

The AcroTherm is contraindicated for patients under the age of 18 and for patients with peripheral vascular disease.

	Predicate	Predicate	Predicate
	AQUARIUS MEDICAL CORPORATION	AQUARIUS MEDICAL CORPORATION	MIRE
Product	AcroTherm	Thermo-Stat K970367	Allon 2001 K001546
Intended Use	Patient Temp. Control Hypothermia	Patient Temp. Control Hypothermia	Patient Temp. Control Hypo/hyperthermia
Intended Population	Adult patients	Adult patients	Adult and pediatric patients
Prescription Device Only	Yes	Yes	Yes
Use Environment	Hospitals and healthcare facilities	Hospital	Hospital
Design/Features:			
Type	Neg Pressure/ Water Perf Pad ✓	Neg Pressure/ Therm Pad	Hot Water Perfusion Pad
Pressure Device	Yes-neg	Yes-neg	No
Sub-atmospheric pressure (mmHg)	40±5 <i>pulsating</i>	40-60 <i>constant</i>	NA
Electric (AC)	Yes	No	Yes
Temp. Range	≤45 °C <i>113 °F</i>	≤45 °C	≤40.2 °C <i>104 °F</i>
Application Site	Distal-Limb	Distal-Limb	Up to Whole Body
Disposable Type	Limb Cover	Thermal Pad/Seal	Perfusion Pad
Control System:			
Controller Type	Micro-logic	NA	Micro-Processor
Size	14x6x5in	NA	103x21x20in
Weight	<5lb	NA	73lb

1 ATM = 760 mmHg

*760
- 720
40 mmHg*

*760
- 40
720*

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Premarket Notification 510(k)

AcroTherm

Section 2-Certifications and Summaries

Aquarius Medical Corporation

16047 North 82nd Street

Scottsdale, Arizona 85260

Non-Confidential Summary of Safety and Effectiveness

Page 3 of 3
27-Oct-00

		Predicate	Predicate
	AQUARIUS MEDICAL CORPORATION	AQUARIUS MEDICAL CORPORATION	MTR
Product	AcroTherm	Thermo-Stat K970367	Allon 2001 K001546
Mobility	Hand-held	NA	4 wheels
Water Tank	450 – 500 ml	NA	6 Liter
Flow Rate	< 500 ml/min	NA	2-1.25L/min
Safety			
High Temp Alarm	Yes	No	Yes
Water Level	Yes	NA	Yes
Chamber Sub-atmospheric pressure	Yes	Light	NA
Seal Pressure	Yes	Light	NA
Materials			
Chamber	ABS	Polycarbonate	NA
Heating Pad	Urethane	PVC	
Disposable	Urethane	PVC	
Contraindications	Patients under 18. Patients with peripheral vascular disease.	Patients under 18. Patients with peripheral vascular disease	Patients with open, widespread skin lesions that will contact the device or patients with multiple trauma

Differences between Other Legally Marketed Predicate Devices:

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicates.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2001

Aquarius Medical Corporation
c/o Mr. Mike McCaulcy
President
16099 North 82nd Street
Suite B-1
Scottsdale, AZ 85260

Re: K003368

Trade Name: AcroTherm™

Regulatory Class: II (two)

Product Code: DWJ

Dated: January 2, 2001

Received: January 4, 2001

Dear Mr. McCaulcy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

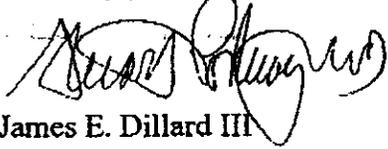
375

Page 2 – Mr. Mike McCauley

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-5648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,


for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Premarket Notification 510(k)
Section 2-Certifications and Summaries

AcroTherm

2.3 Indications for Use

510(k) Number: K003368 (-To be assigned)

Device Name: AcroTherm

Intended Use: The AcroTherm is designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K003368

Division of Cardiovascular & Respiratory Devices
510(k) Number K003368

Prescription Use
(Per CFR 801.109)

or

Over-the-Counter Use

377

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

DATE 6-16-04

From: Reviewer(s) - Name(s) KEITH FONG

Subject: 510(k) Number 1040911/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices NA
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
 No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

DWJ - System, Thermal Regulative

870.5900 class II
Review: [Signature] ASDB 6/21/04
(Branch Code) (Date)

Final Review: [Signature] for BDE 6/22/04
(Date)

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

K040911/S001

Reviewer: Keith Foy, MS
Materials/Mechanical Engineer
Division/Branch: DCD
(HFZ-450)
Proprietary Trade Name: "VITALHEAT" DEVICE MADE BY DYNATHERM
MEDICAL, INC.

Common Name: DWJ – System, Thermal Regulating; §870.5900 Class II

Product to which compared:

(K003368) – AcroTherm – "...is designed to Non-Invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage."

3rd Party: Underwriters Laboratories, Inc.
1655 Scott Blvd.

Santa Clara, CA 95050-4169

Phone: (408)876-2566

FAX: (408)556-6217

Contact: Morten Simon Christensen, Staff Engineer & FDA 510(k) office coordinator

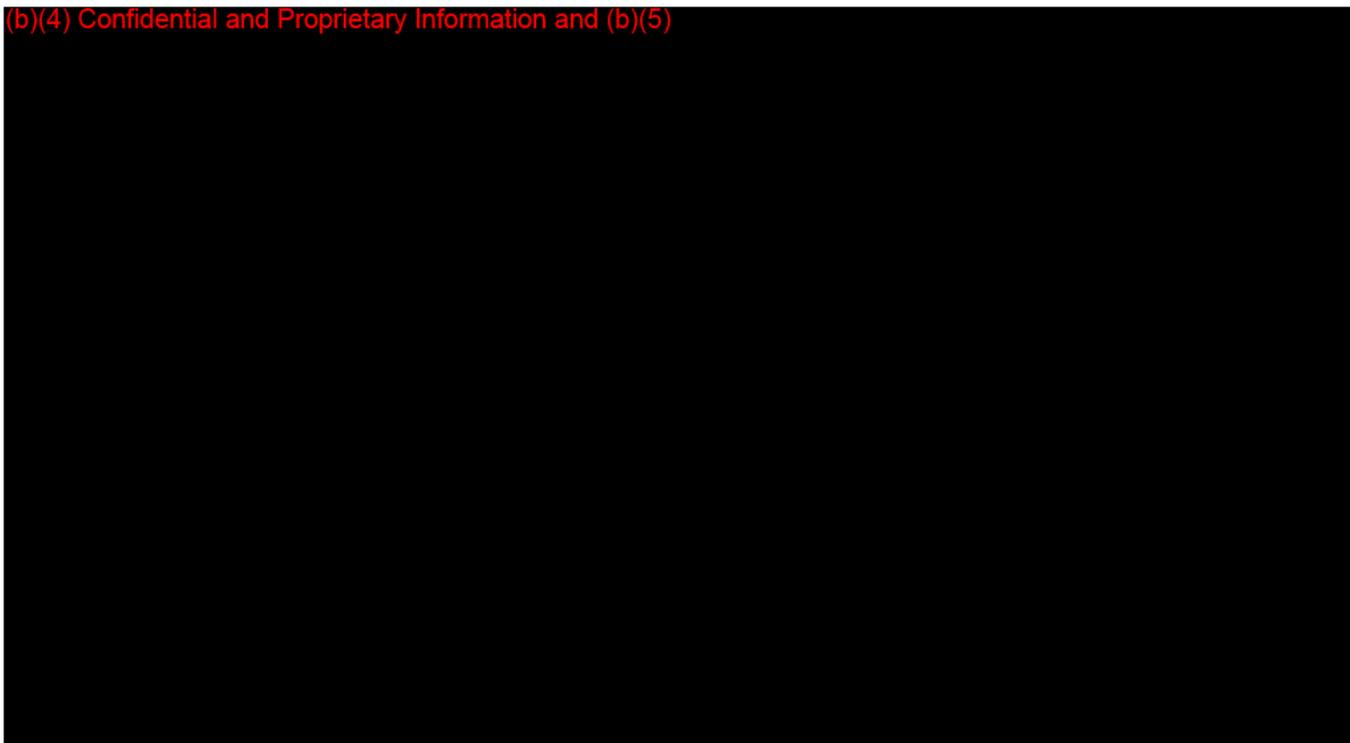
Applicant: Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010

Decision: SE

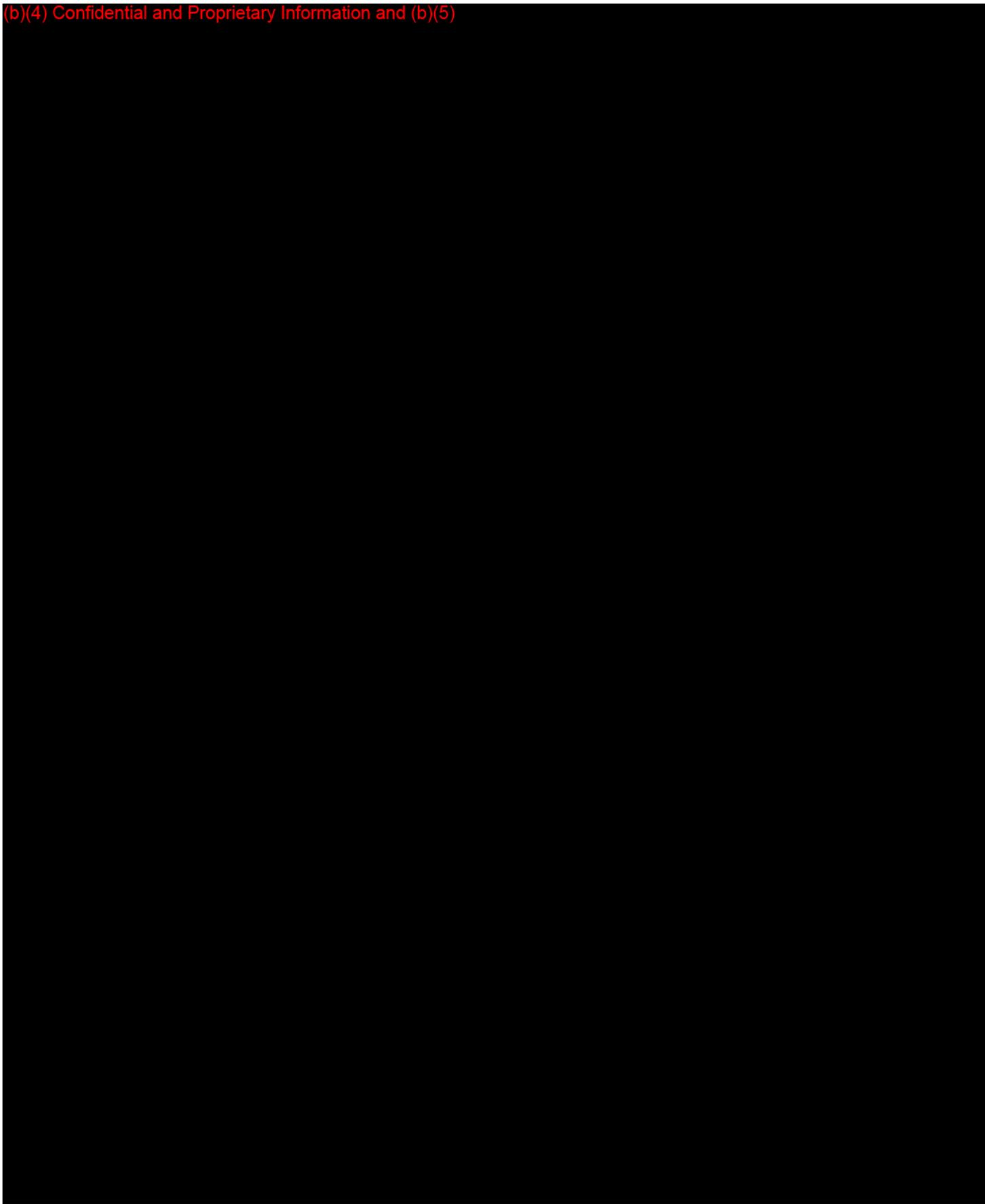
Indications for Use

The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by warming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

(b)(4) Confidential and Proprietary Information and (b)(5)

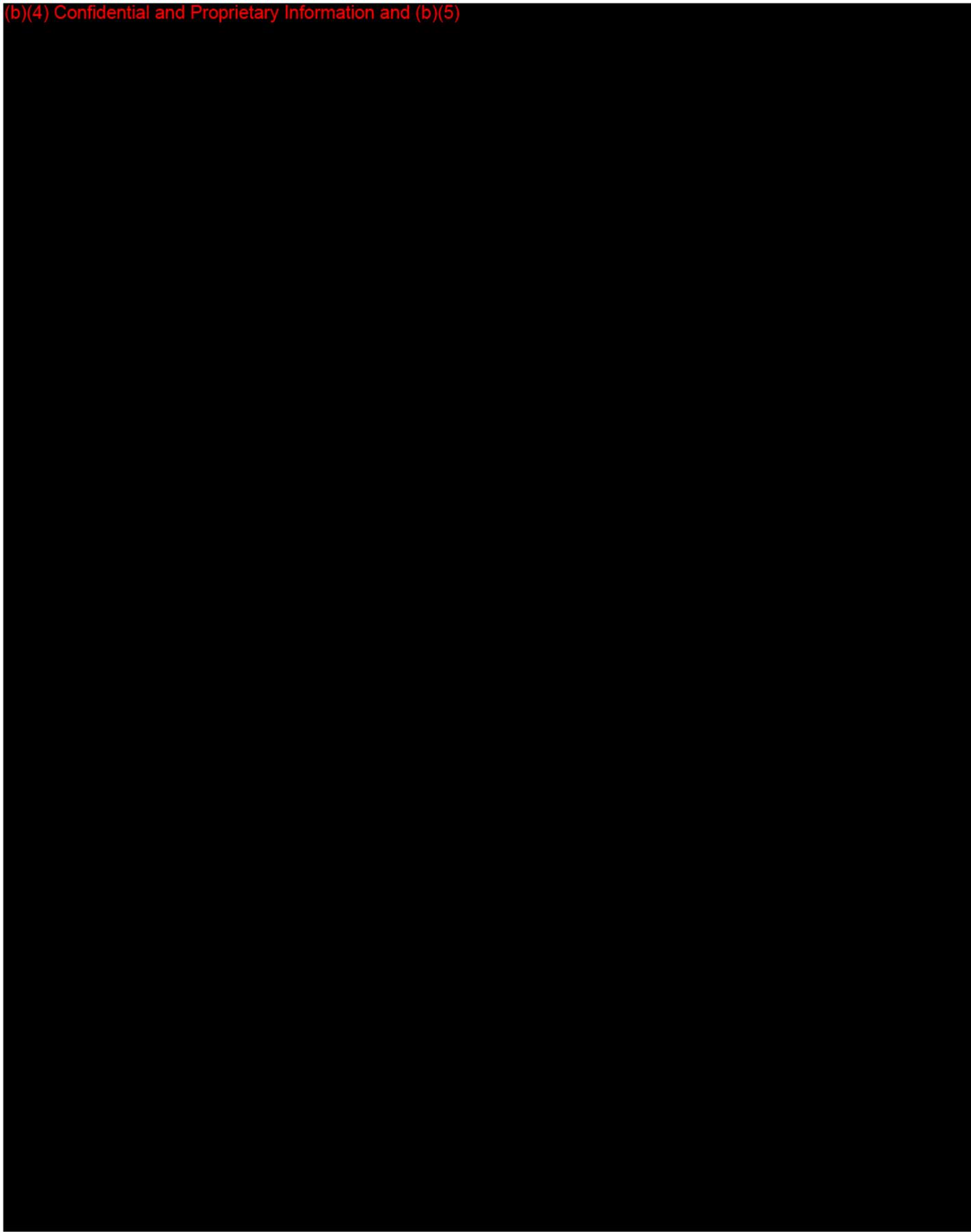


(b)(4) Confidential and Proprietary Information and (b)(5)



7

(b)(4) Confidential and Proprietary Information and (b)(5)



(b)(4) Confidential and Proprietary Information and (b)(5)

Substantial Equivalence (SE) Decision Making Documentation

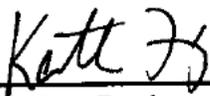
	YES	NO	
1. IS PRODUCT A DEVICE?	<u>X</u>	—	IF NO, STOP
2. DEVICE SUBJECT TO 510(k)?	<u>X</u>	—	IF NO, STOP
3. SAME INDICATION STATEMENT?	<u>X</u>	—	IF YES, GO TO 5
5. SAME TECHNOLOGICAL CHARACTERISTICS?	<u>X</u>	—	IF YES, GO TO 7
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	<u>X</u>	—	IF YES, STOP -> SE

Reviewer Recommendation: SE

ProCode: DWJ – System, Thermal Regulating;
Class: Class II §870.5900

Keith Foy, MS
Mechanical/Materials Engineer, DCRD/CSPB

Date June 16, 2004



Keith Foy, Reviewer CSPB



Dina Fleischer, Branch Chief CSPB

Indications for Use

510(k) Number (if known): K040911

Device Name: VitalHeat™

Indications For Use:

The VitalHeat™ is designed to Non-Invasively treat hypothermic patients by warming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Prescription Use X
(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 1

4-23-04

From: Reviewer(s) - Name(s) KETH Foy - 3RD PARTY

Subject: 510(k) Number K040911

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept). *FIXED Deficiencies 4-23-04 KCF*
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- | | | |
|---|------------------------------|-----------------------------|
| Is this device subject to Section 522 Postmarket Surveillance? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Is this device subject to the Tracking Regulation? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Was clinical data necessary to support the review of this 510(k)? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Is this a prescription device? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Was this 510(k) reviewed by a Third Party? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Special 510(k)? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) _____

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

Review: Diana R. Vachner for DF CSPB 4/23/04
(Branch Chief) (Branch Code) (Date)

Final Review: Diana R. Vachner for BDZ 4/23/04
(Division Director) (Date)

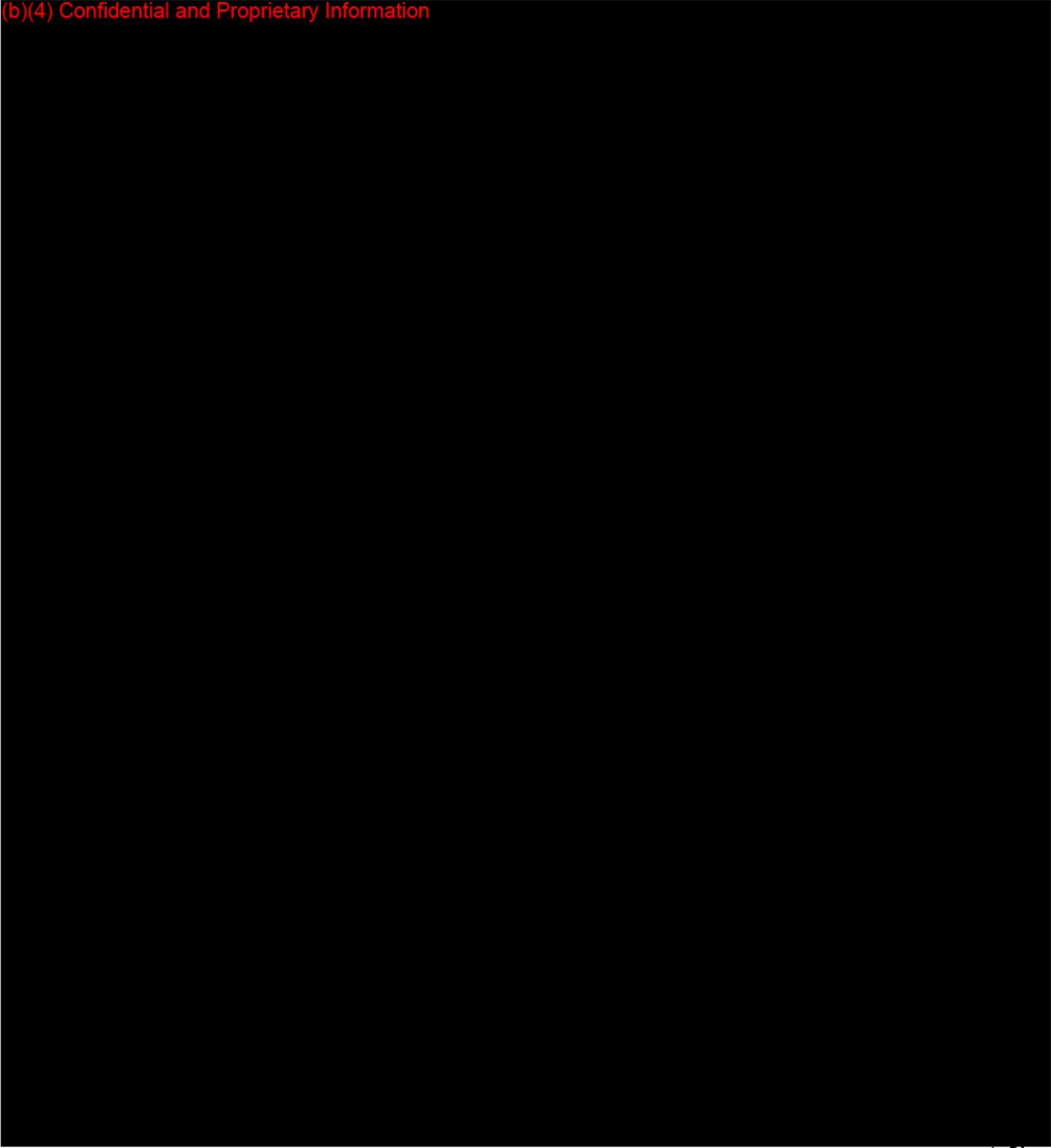
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

From: Foy, Keith
Sent: Friday, April 23, 2004 10:04 AM
To: Foy, Keith
Cc: Letzing, William G.; Fleischer, Dina J.
Subject: K040911 - VITALHEAT Warming device

Ms. Klinker,

Here are comments/deficiencies regarding the above referenced 3rd party review. The file has been placed on hold until a hard copy response to these deficiencies is received. Please review these and contact myself and/or Mr. Bill Letzing at (301)443-8320 if you have any questions.

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



Sincerely,

Keith E. Fog

kxf@cdrh.fda.gov

(301)443-8243 x157

(301)480-4204 FAX



Records processed under FOIA Request #2016-6393; Released by CDRH on 09-12-2016.

*** TX REPORT ***

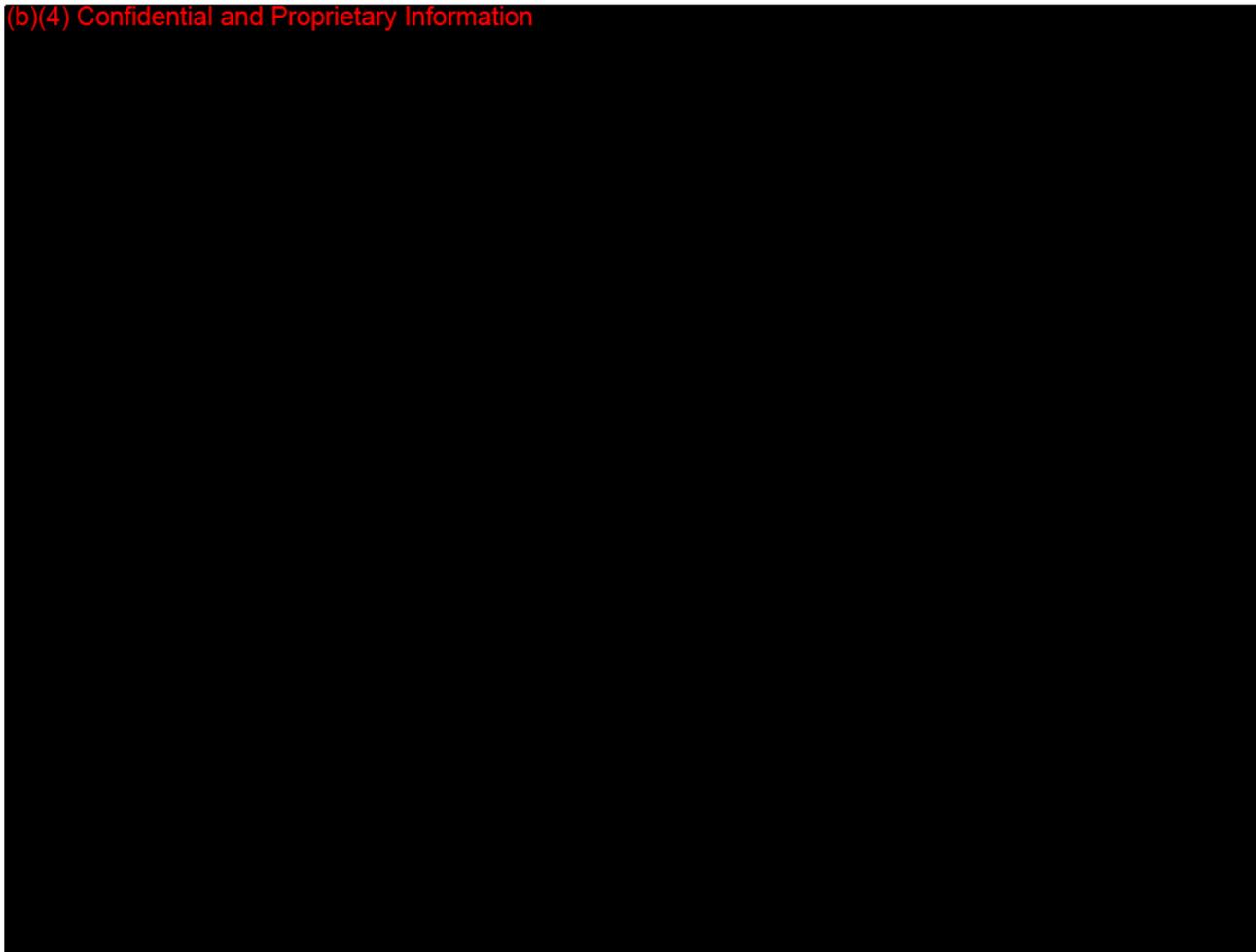
TRANSMISSION OK

TX/RX NO	2420	
CONNECTION TEL		914085566217
SUBADDRESS		
CONNECTION ID		
ST. TIME	04/23 09:14	
USAGE T	01'03	
PGS.	2	
RESULT	OK	

From: Foy, Keith
Sent: Friday, April 23, 2004 10:04 AM
To: Foy, Keith
Cc: Letzing, William G.; Fleischer, Dina J.
Subject: K040911 - VITALHEAT Warming device

Ms. Klinker,
 Here are comments/deficiencies regarding the above referenced 3rd party review. The file has been placed on hold until a hard copy response to these deficiencies is received. Please review these and contact myself and/or Mr. Bill Letzing at (301)443-8320 if you have any questions.

(b)(4) Confidential and Proprietary Information



K040911 - 3rd Party Review

Reviewer: Keith Foy, MS
Materials/Mechanical Engineer

Division/Branch: DCD
(HFZ-450)

Proprietary Trade Name: "VITALHEAT" DEVICE MADE BY DYNATHERM MEDICAL, INC.

Common Name: DWJ – System, Thermal Regulating; §870.5900 Class II

Product to which compared:

(K003368) – AcroTherm – "...is designed to Non-Invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage."

3rd Party: Underwriters Laboratories, Inc.

1655 Scott Blvd.

Santa Clara, CA 95050-4169

Phone: (408)876-2566

FAX: (408)556-6217

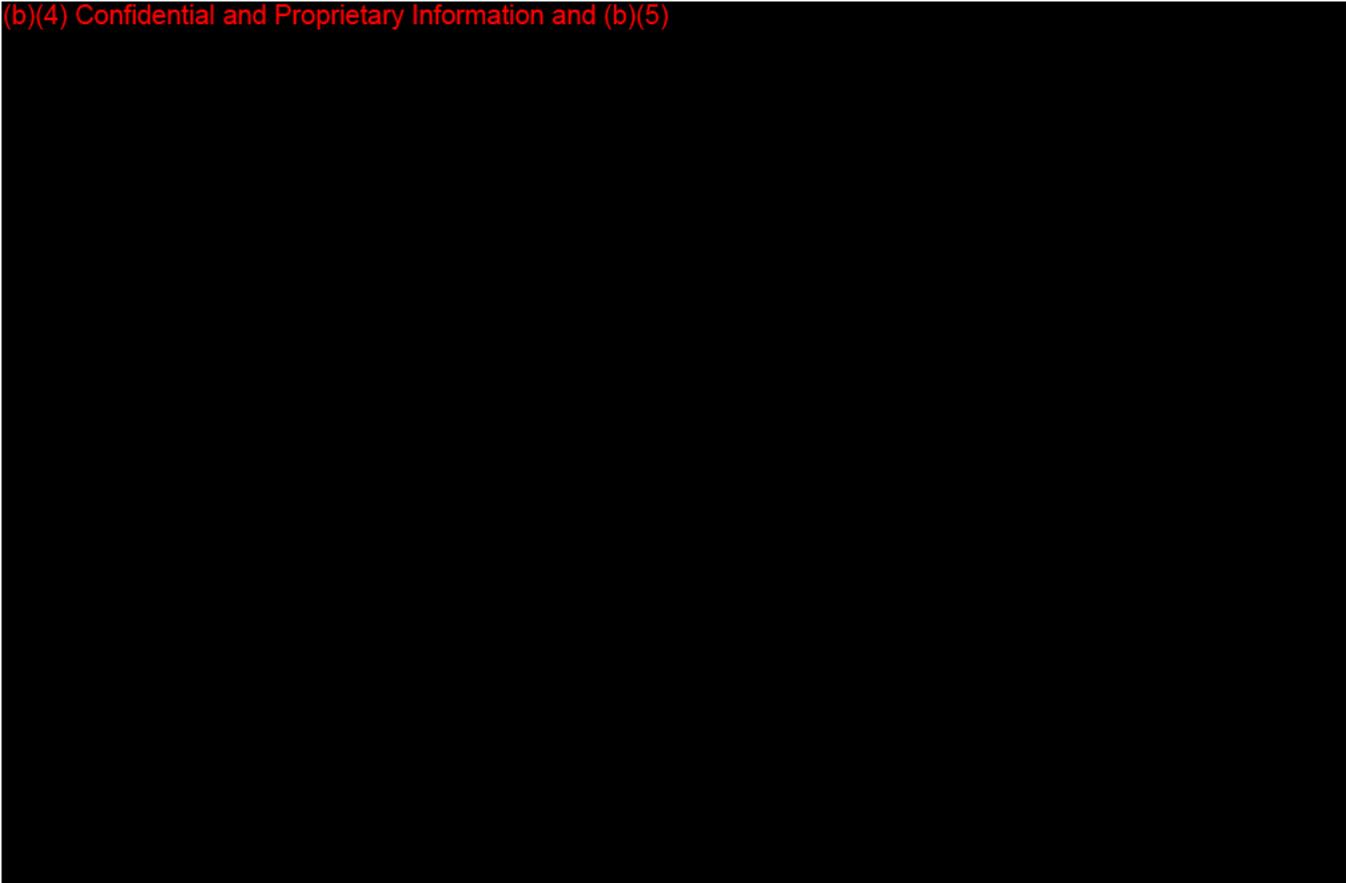
Contact: Denise Klinker, Principal Reviewer

Applicant: Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010

Indications for Use (modified from proposed Intended Use)

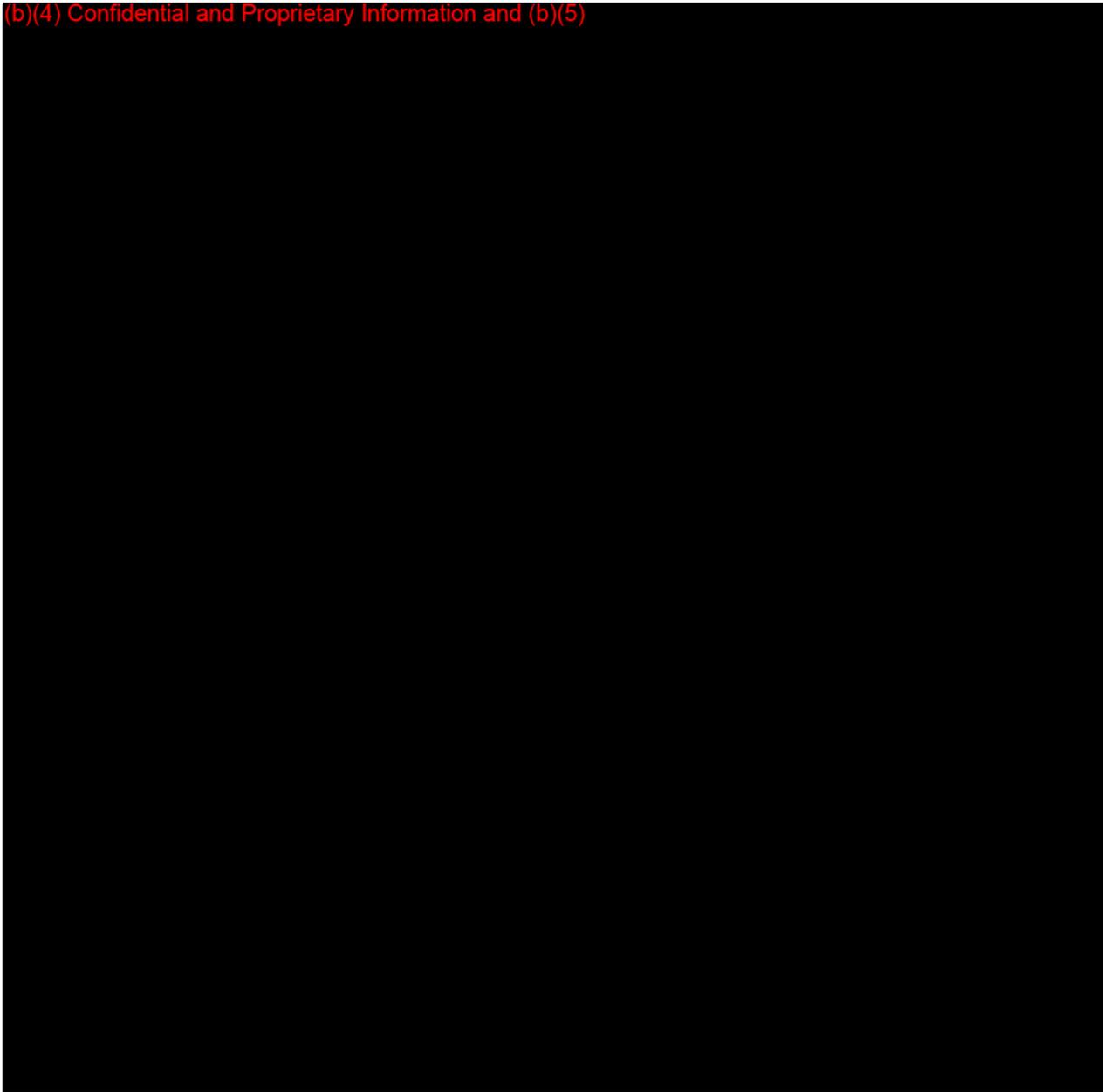
"...is designed to Non-Invasively treat *mildly* hypothermic patients by warming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to hand."

(b)(4) Confidential and Proprietary Information and (b)(5)



K040911

(b)(4) Confidential and Proprietary Information and (b)(5)



Keith J 4-23-04

71

Foy, Keith

From: Foy, Keith
Sent: Thursday, April 22, 2004 2:16 PM
To: Letzing, William G.
Cc: Foy, Keith
Subject: RE: K040911-Third Party review

(b) (5), (b) (4)



Keith E. Foy
kxf@cdrh.fda.gov
(301)443-8243 x157
(301)480-4204 FAX

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

From: Letzing, William G.
Sent: Thursday, April 22, 2004 1:35 PM
To: Foy, Keith
Subject: RE: K040911-Third Party review

OK, I just sent it.

Thanks,

Bill

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

From: Foy, Keith
Sent: Tuesday, April 20, 2004 11:10 PM
To: Letzing, William G.
Subject: K040911-Third Party review

Bill,

Dina asked me to take care of the 3rd party document that you reviewed for her. Please forward me your email from April 14th so I can forward this to the 3rd party.

Thanks!

Keith E. Foy
kxf@cdrh.fda.gov
(301)443-8243 x157
(301)480-4204 FAX

72

Foy, Keith

From: Letzing, William G.
Sent: Thursday, April 22, 2004 1:34 PM
To: Foy, Keith
Subject: FW: THIRD PARTY (UL) REVIEW OF K040911, DYNATHERM INC.'S VITALHEAT DEVICE

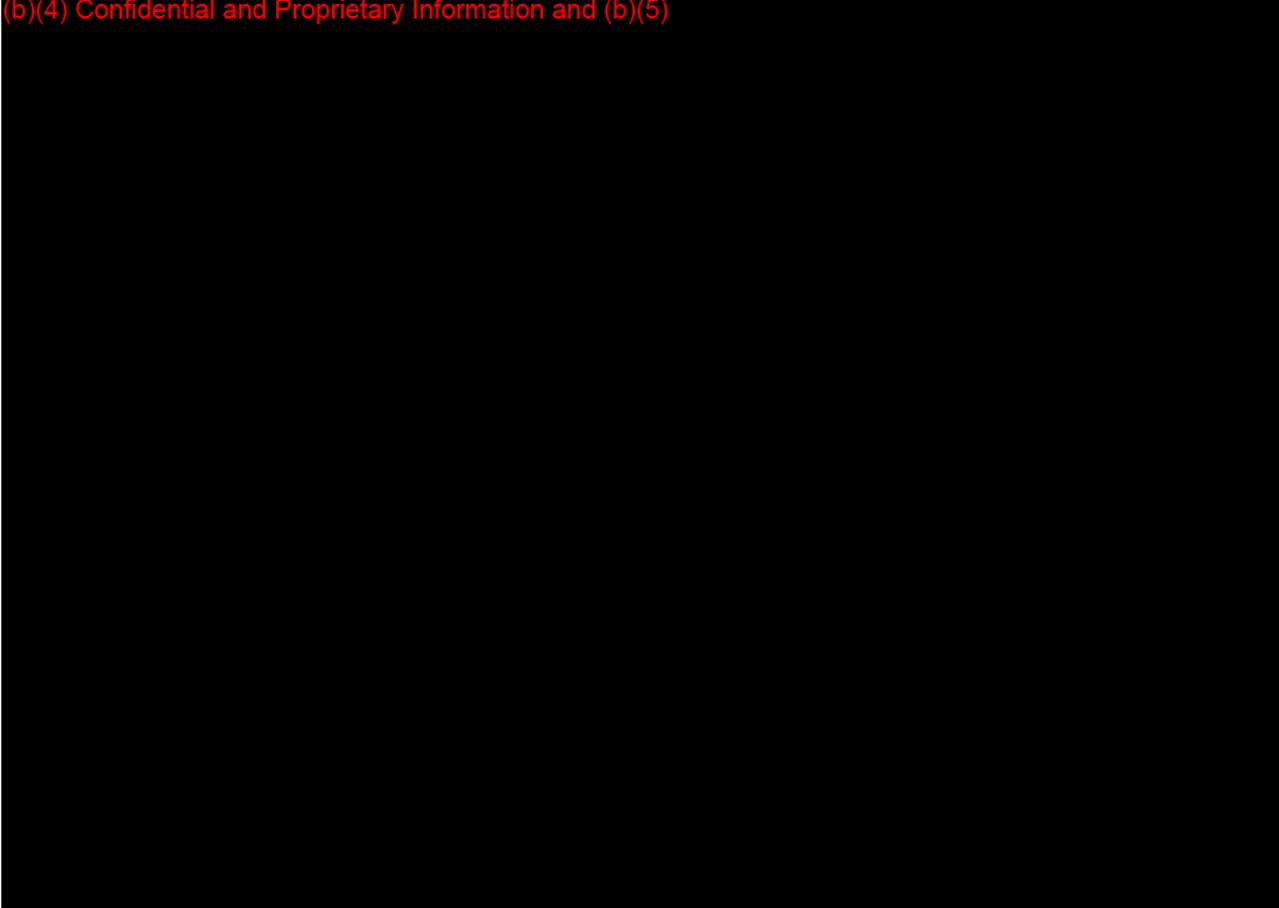
-----Original Message-----

From: Letzing, William G.
Sent: Wednesday, April 14, 2004 5:13 PM
To: Fleischer, Dina J.
Subject: THIRD PARTY (UL) REVIEW OF K040911, DYNATHERM INC.'S VITALHEAT DEVICE

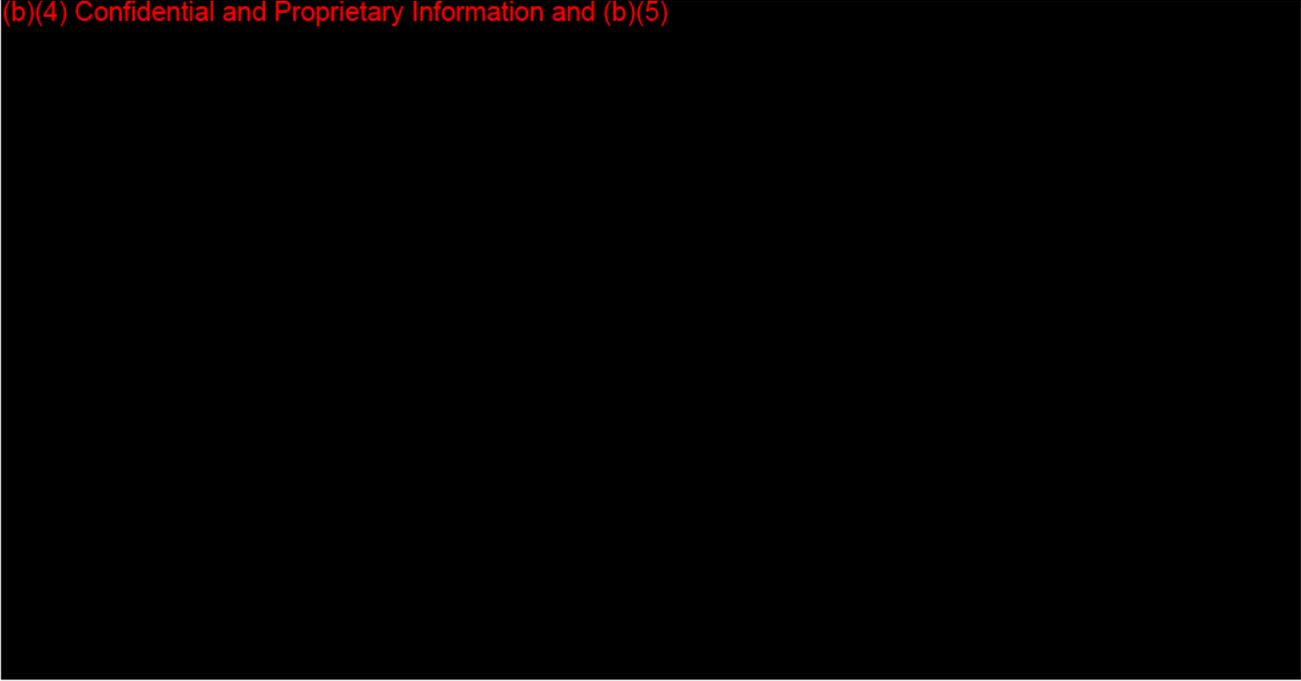
REVIEW OF UNDERWRITERS LABORATORY (THIRD PARTY) REVIEW OF K040911
FOR THE
"VITALHEAT" DEVICE MADE BY DYNATHERM MEDICAL, INC.

This device is a controlled warm water loop and vacuum system which attaches to the hand of a hypothermic patient and supplies heat and a partial vacuum (so as to dilate the vasculature) for the purpose of raising the patient's core temperature. The subject and predicate devices are similar, with a major difference being the mitt or heating pad that attaches to the patient. The predicate mitt contains two warm water polymeric perfusion pads in contact with the patient's hand and forearm, both on the top and bottom. The subject VitalHeat mitt applies only one polymeric perfusion pad to the hand and it has an aluminum surface or paddle on one side that acts as a heat sink to warm the patient's palm.

(b)(4) Confidential and Proprietary Information and (b)(5)



(b)(4) Confidential and Proprietary Information and (b)(5)



W. Letzing

4/14/04

74

Foy, Keith

From: Letzing, William G.
Sent: Thursday, April 22, 2004 1:34 PM
To: Foy, Keith
Subject: FW: THIRD PARTY (UL) REVIEW OF K040911, DYNATHERM INC.'S VITALHEAT DEVICE

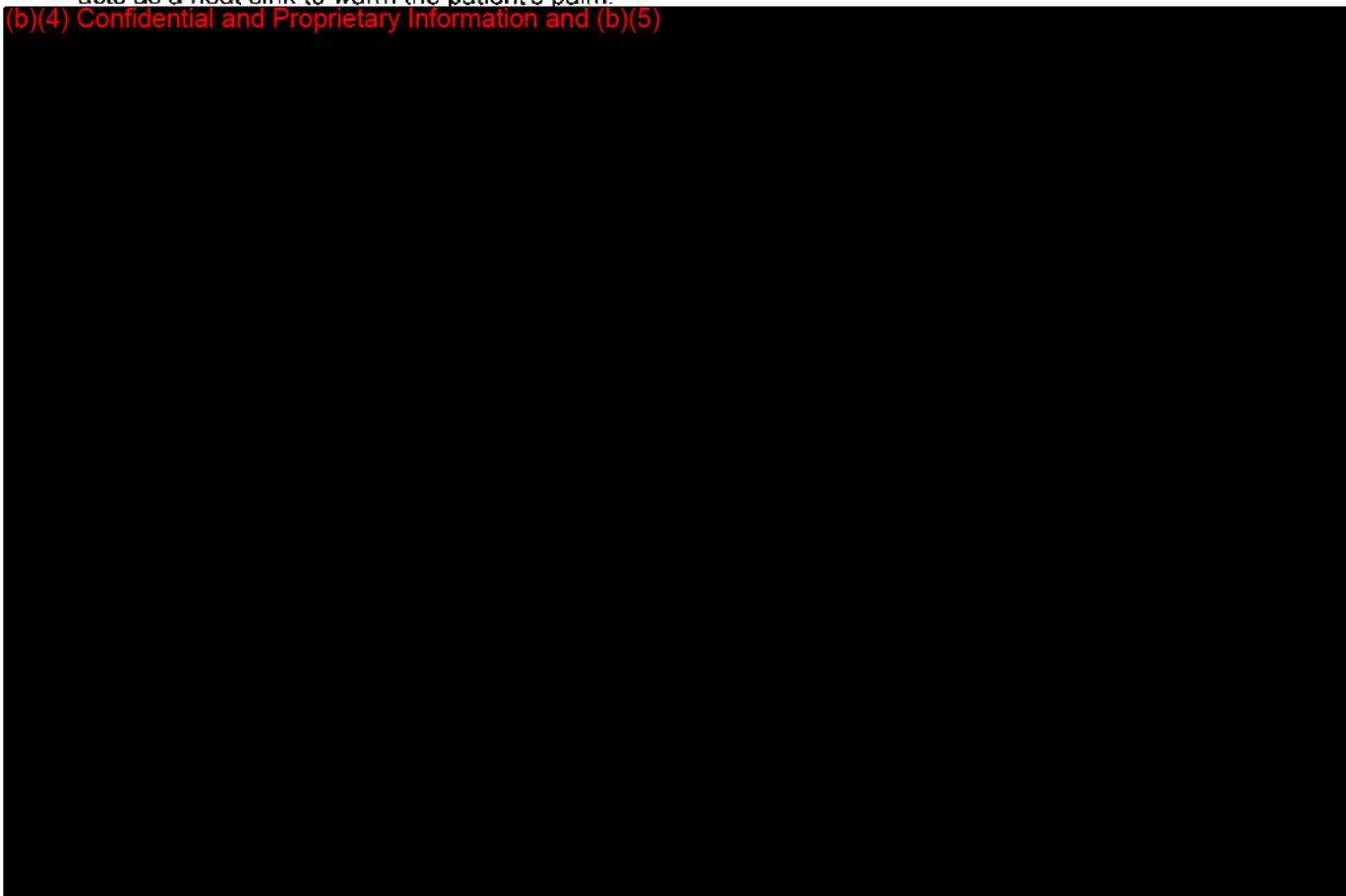
-----Original Message-----

From: Letzing, William G.
Sent: Wednesday, April 14, 2004 5:13 PM
To: Fleischer, Dina J.
Subject: THIRD PARTY (UL) REVIEW OF K040911, DYNATHERM INC.'S VITALHEAT DEVICE

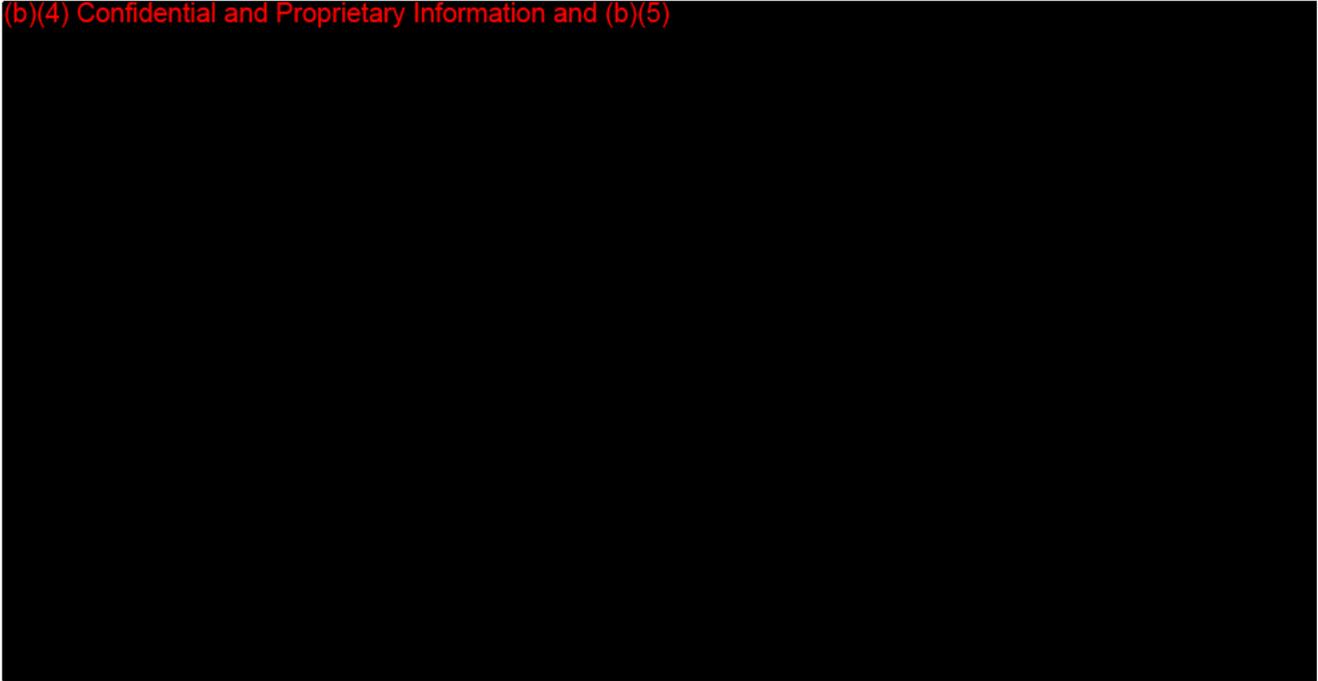
REVIEW OF UNDERWRITERS LABORATORY (THIRD PARTY) REVIEW OF K040911
FOR THE
"VITALHEAT" DEVICE MADE BY DYNATHERM MEDICAL, INC.

This device is a controlled warm water loop and vacuum system which attaches to the hand of a hypothermic patient and supplies heat and a partial vacuum (so as to dilate the vasculature) for the purpose of raising the patient's core temperature. The subject and predicate devices are similar, with a major difference being the mitt or heating pad that attaches to the patient. The predicate mitt contains two warm water polymeric perfusion pads in contact with the patient's hand and forearm, both on the top and bottom. The subject VitalHeat mitt applies only one polymeric perfusion pad to the hand and it has an aluminum surface or paddle on one side that acts as a heat sink to warm the patient's palm.

(b)(4) Confidential and Proprietary Information and (b)(5)



(b)(4) Confidential and Proprietary Information and (b)(5)

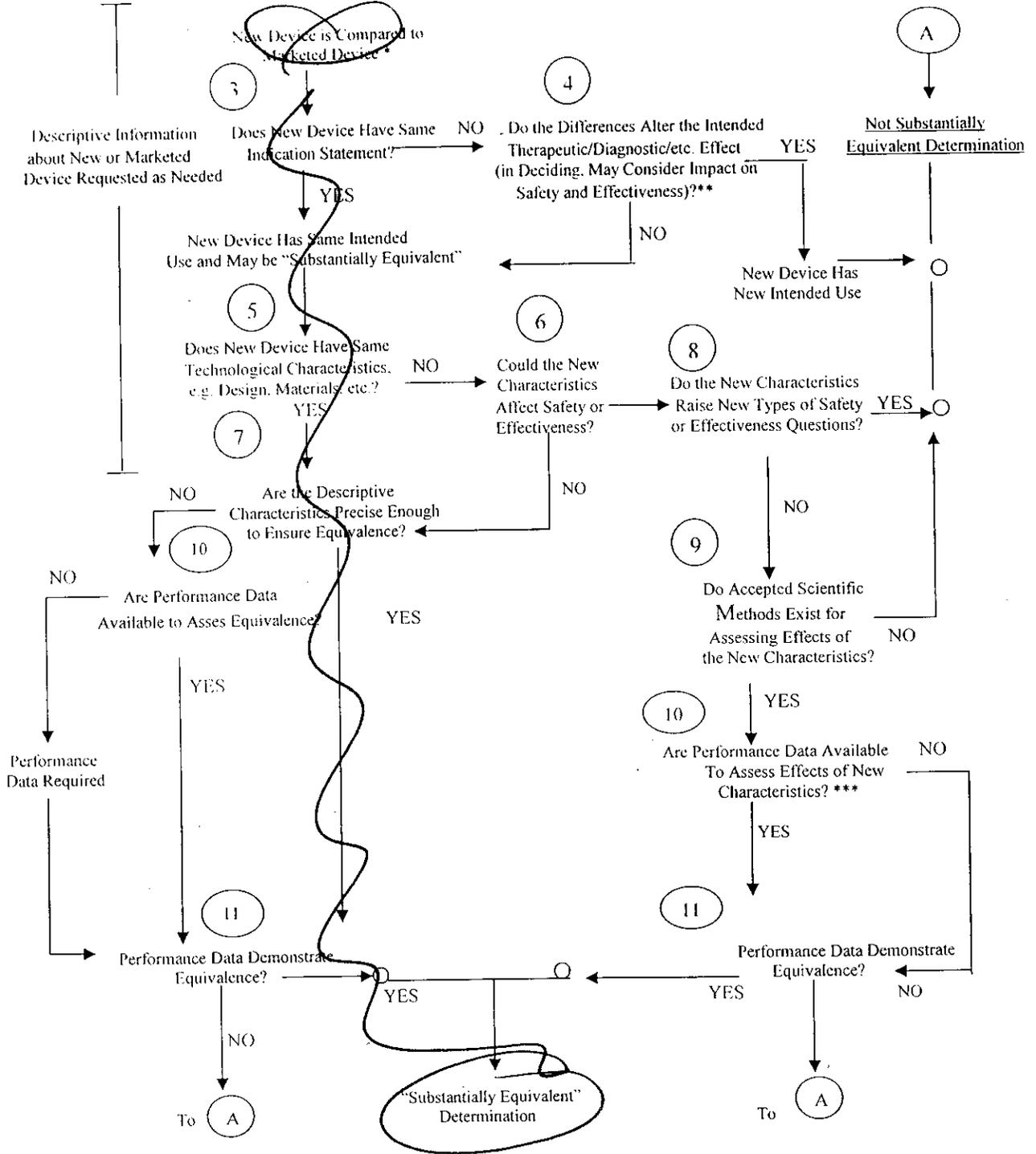


W. Letzing

4/14/04

76

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- * 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

5

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

June 07, 2004

DYNATHERM MEDICAL, INC.
c/o UNDERWRITERS LABORATORIES, INC. 510(k) Number: K040911
1655 SCOTT BLVD. Product: VITALHEAT
SANTA CLARA, CA 95050
ATTN: DENISE LEUNG KLINKER

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.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

//

K040911/51

1655 Scott Boulevard
Santa Clara, CA 95050-4169
United States Country Code (1)
(408) 985-2400
FAX No. (408) 296-3256
Http://www.ul.com



June 3, 2004

CDRH / Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: Additional information. K040911. Third Party 510(K) Submission for Dynatherm Medical Inc., VitalHeat™

Dear Mr. Keith Foy:

In response to FDA's fax dated April 23, 2004, we are submitting additional information from Dynatherm Medical Inc., including our review comments and recommendations.

Enclosed please find:

- 1) Review memo
- 2) Response from the sponsor
- 3) Updated Activity log

Please do not hesitate to contact me should you have questions.

Best Regards,

Morten Simon Christensen
Staff Engineer & FDA 510(k) Office Coordinator
Medical Device Services
Tel: (408) 876-2016
Fax: (408) 556-6218

FDA/CDRH/OCE/PMO
2004 JUN -7 A 11:39

S/K 23

12

June 3, 2004

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

Handwritten notes and stamps, including a date stamp that appears to read "JUN 3 2004".

Subject: Additional information, Third Party 510(K) Review Memo for VitalHeat™, K040911

Name of Sponsor: Dynatherm Medical, Inc.
819 Mitten Road, Suite 42
Burlingame, CA 94010
USA

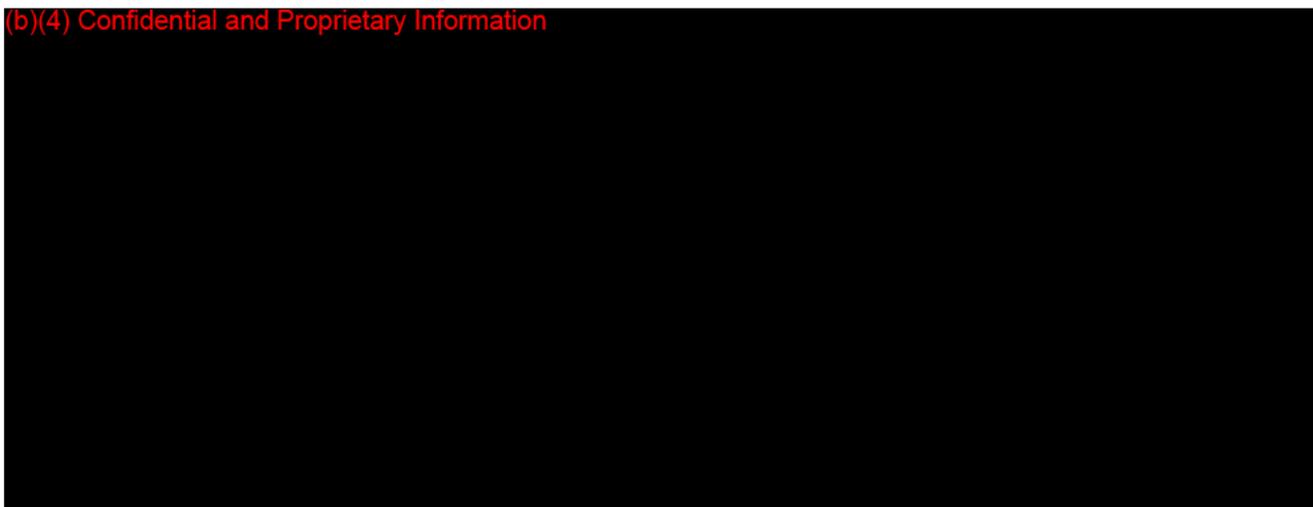
Based on FDA's fax received April 23, 2004, Dynatherm Medical, Inc., has provided additional information. Please find their response as well as our comments below.

Dynatherm Medical has reviewed the Nine (9) questions raised by FDA concerning the above-referenced Premarket Notification, and we believe that the information provided in their response addresses FDA's concerns. FDA questions are in bold letters followed by the sponsor's response and our comments.

For purposes of clarification, Dynatherm Medical is the new owner of Aquarius Medical, the developer of the Acrotherm™ device (K003368). Dynatherm's VitalHeat™ device is an update of the Acrotherm™ device. Indications for use remain the same, and the sponsor has stated in their response that there are no new safety or efficacy issues.

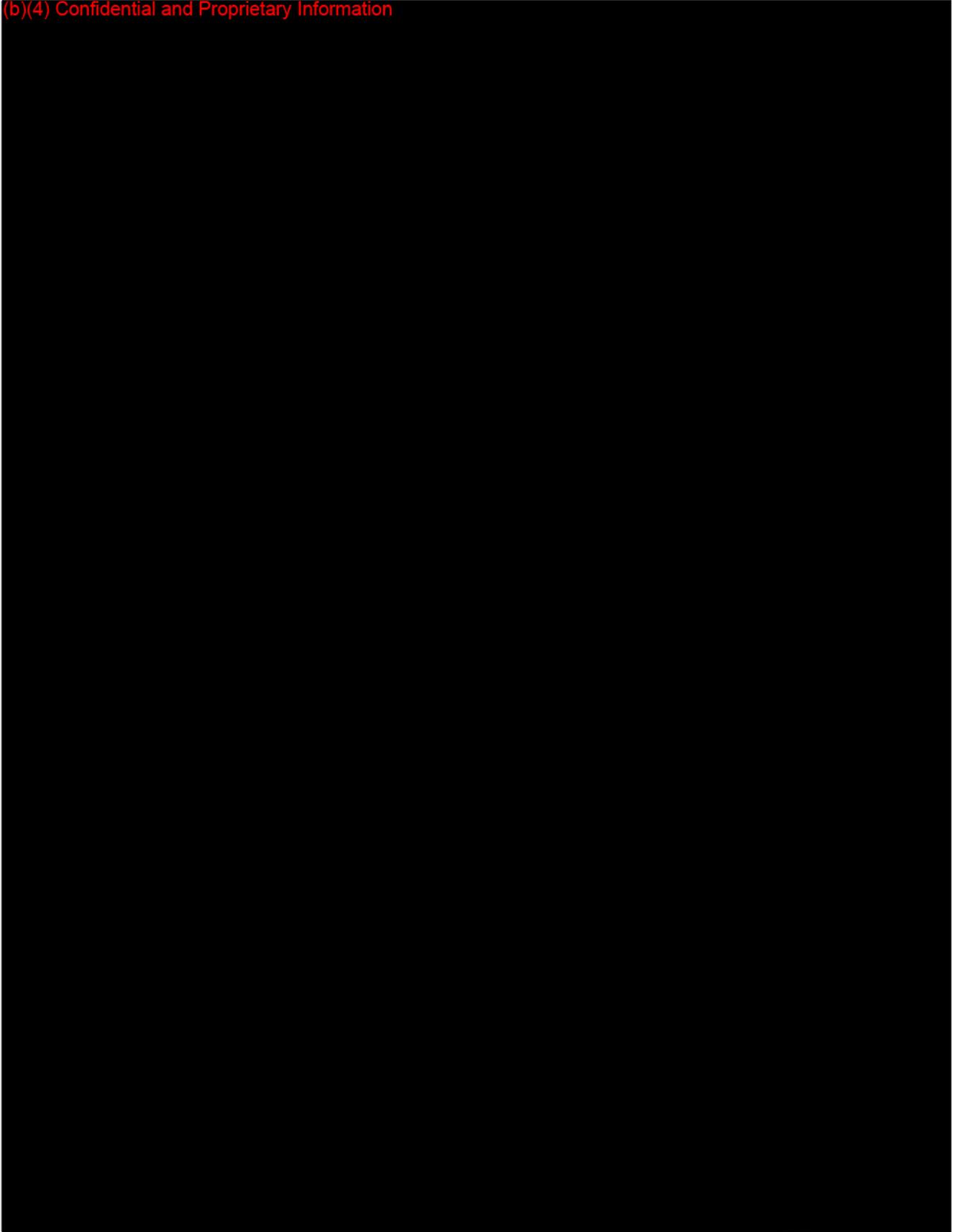
According to the sponsor, the VitalHeat™ device makes certain modifications and improvements on the Acrotherm™ device. These are a) The patient interface is improved for better heat exchange, b) The fluid flow rate is increased for better heat exchange, c) The electronics are modernized for better timer control and patient safety, d) The water system is sealed for operator convenience and to reduce risks associated with spillage including potential electrical and slip and fall risk, and e) The device is more compact.

(b)(4) Confidential and Proprietary Information



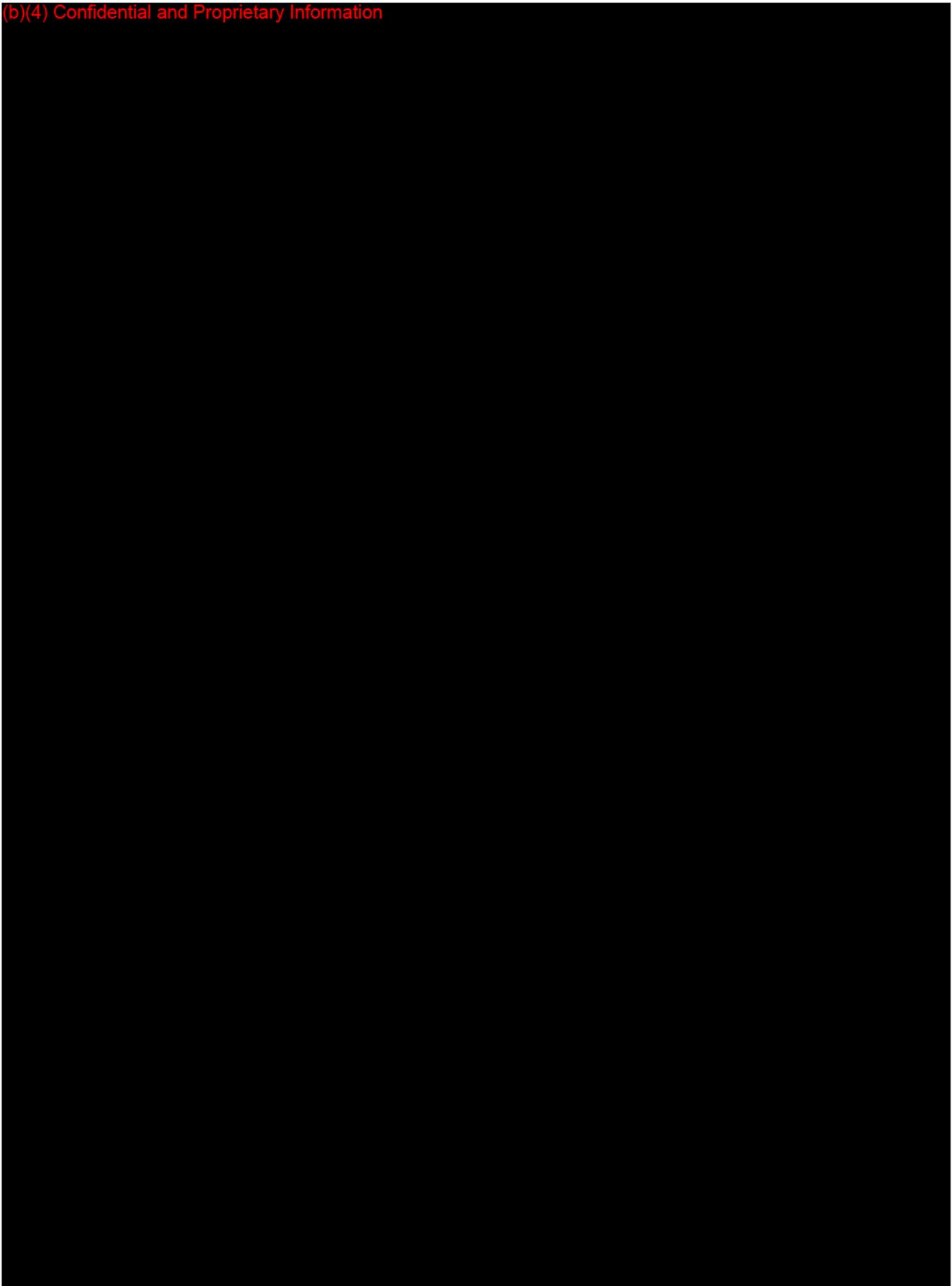
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(b)(4) Confidential and Proprietary Information

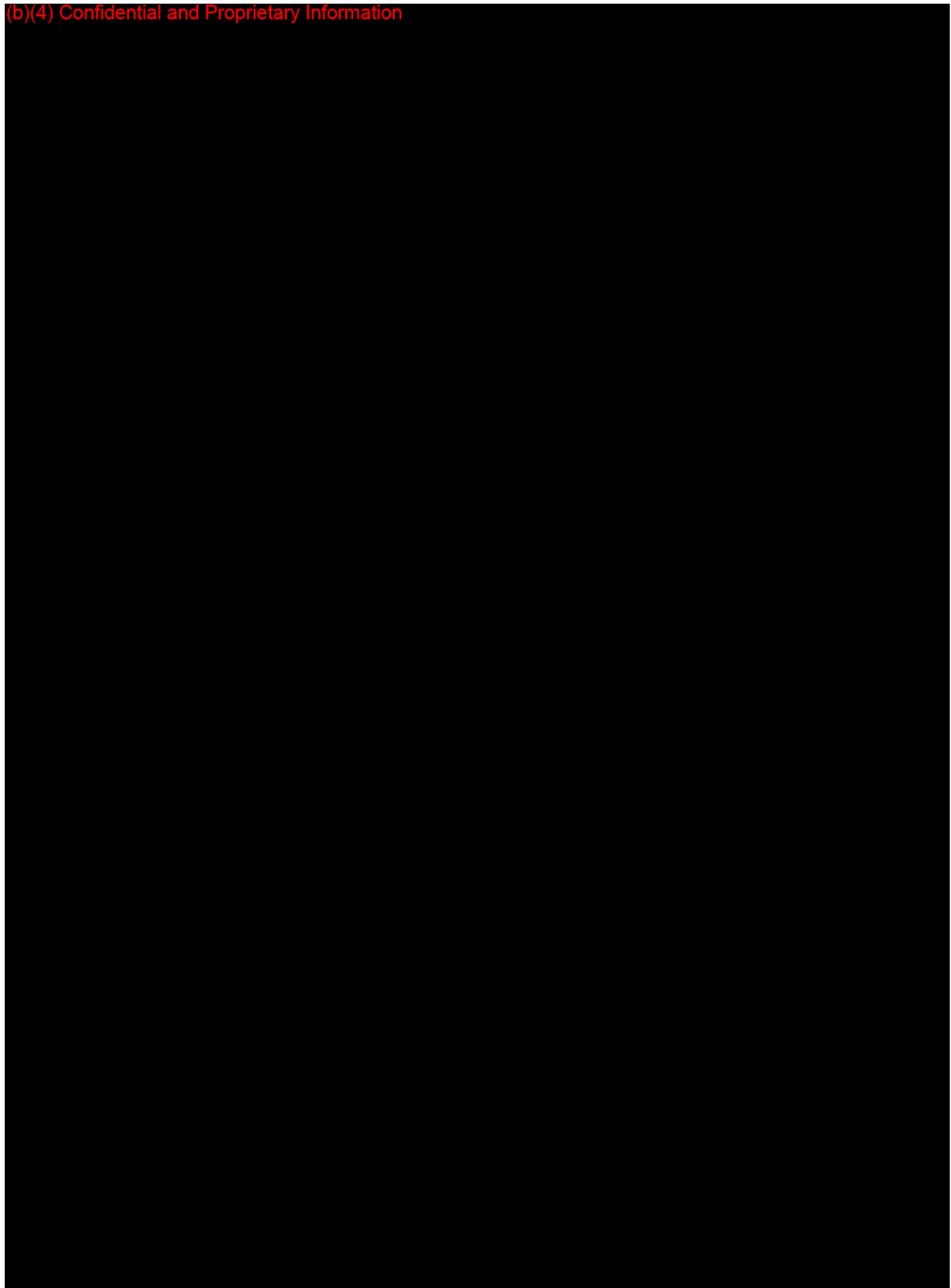


19

(b)(4) Confidential and Proprietary Information

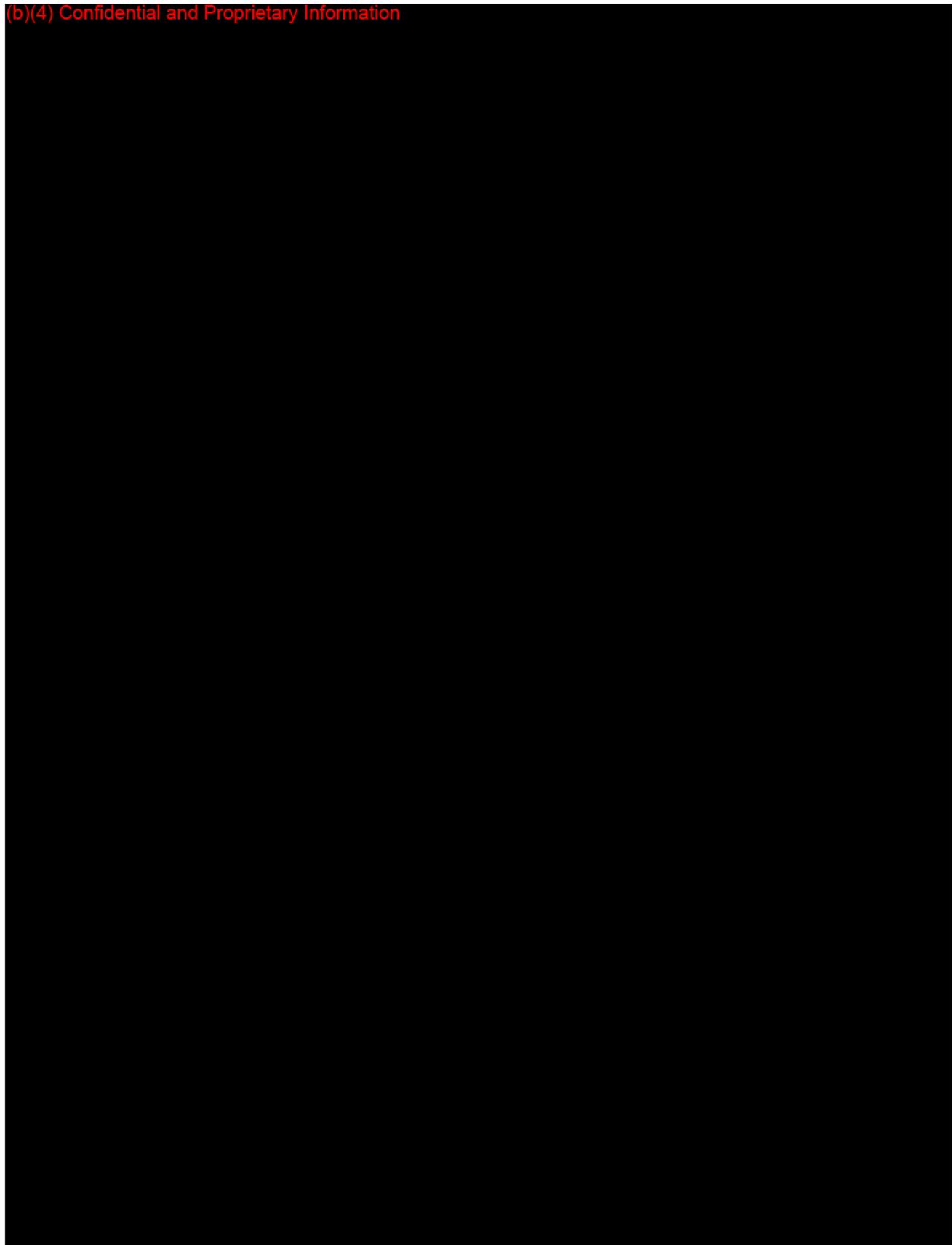


(b)(4) Confidential and Proprietary Information



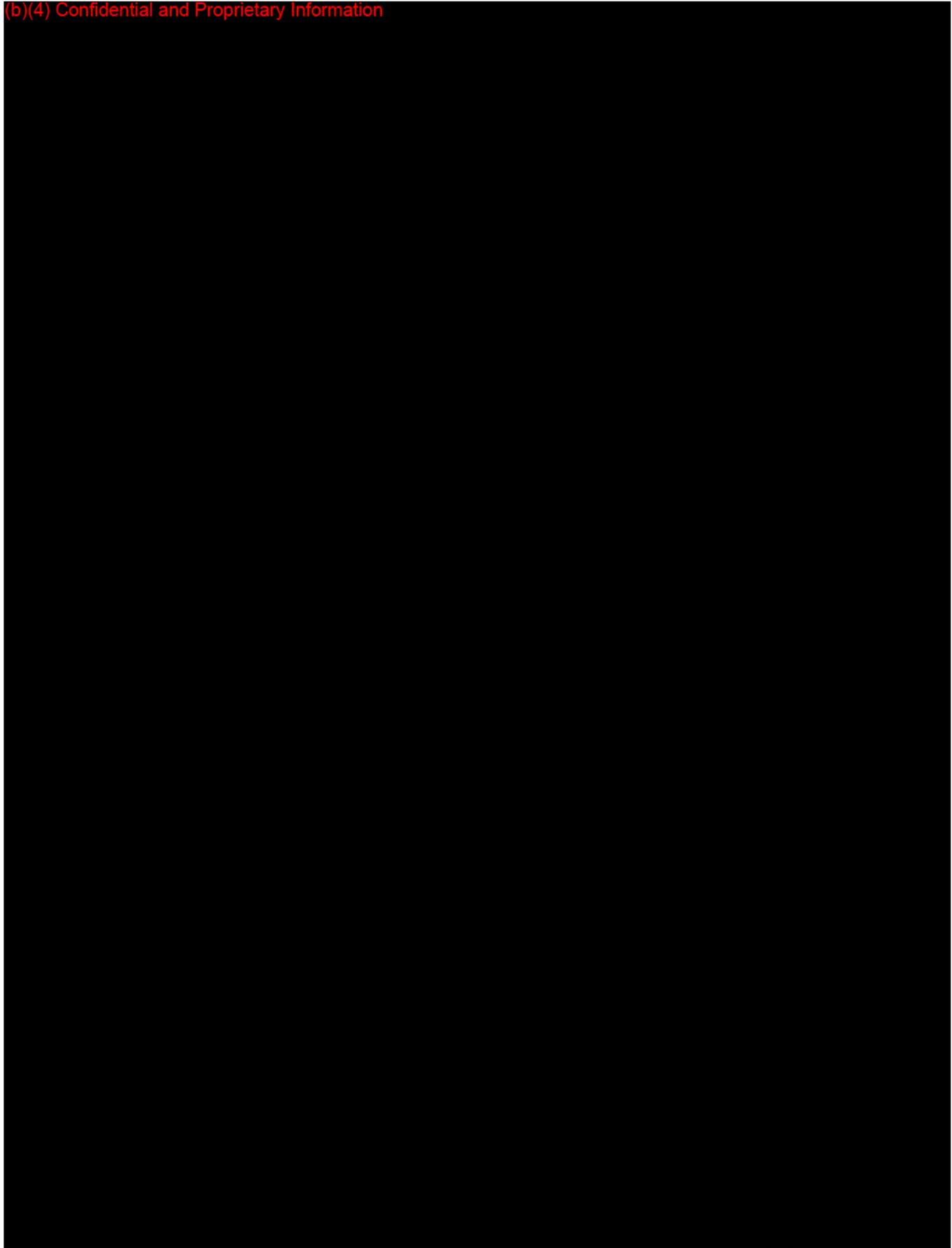
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(b)(4) Confidential and Proprietary Information

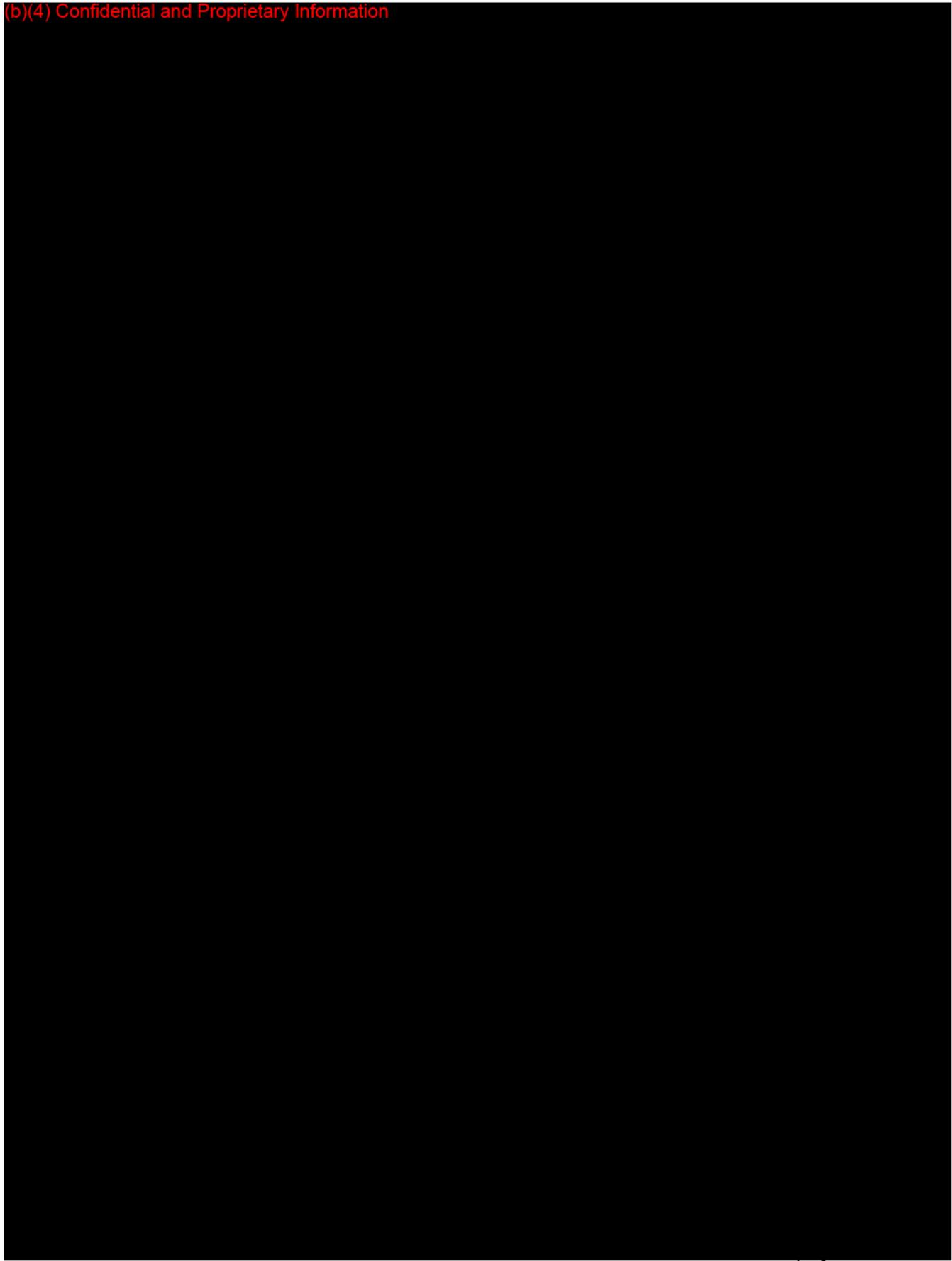


17

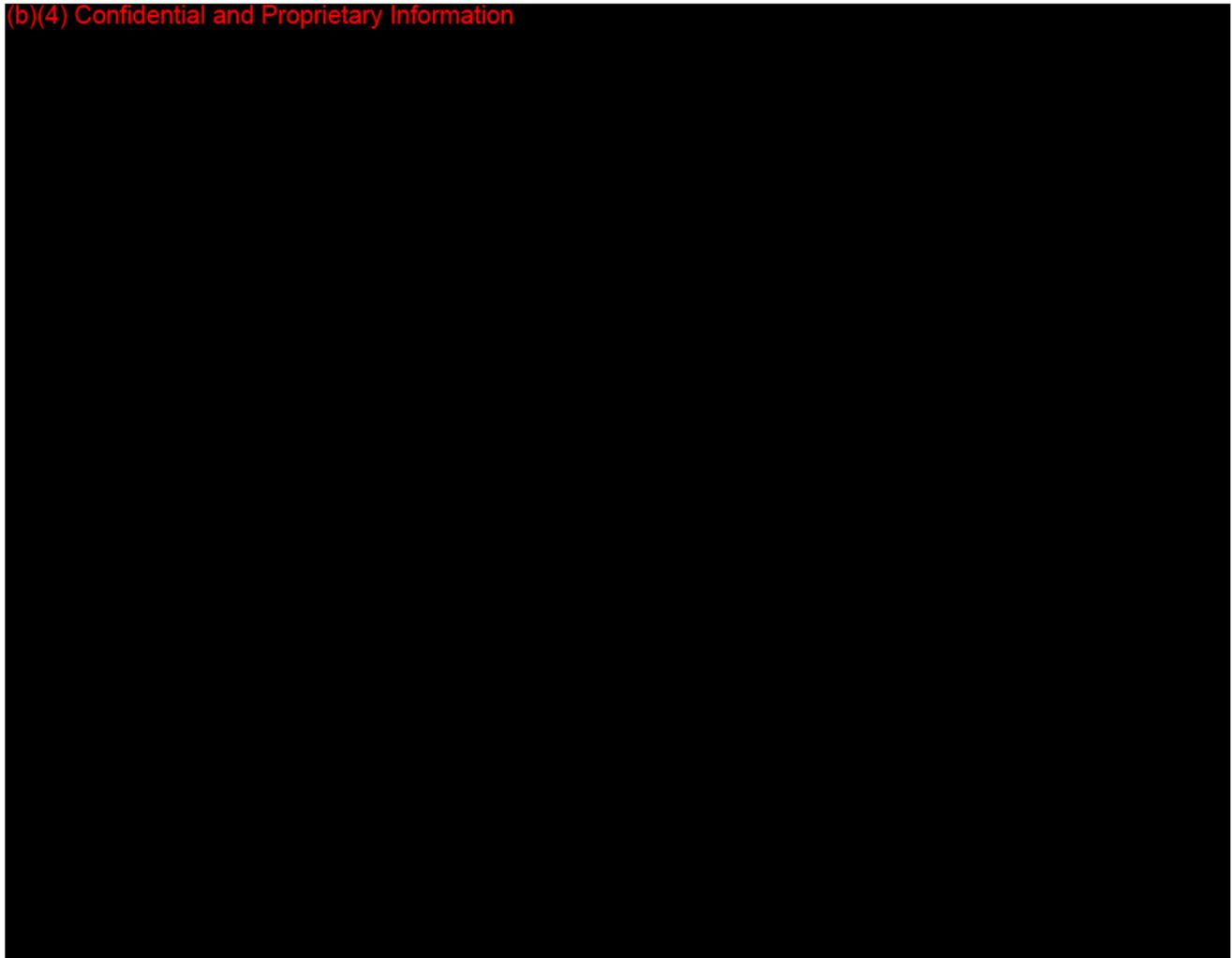
(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



Overall Recommendation:

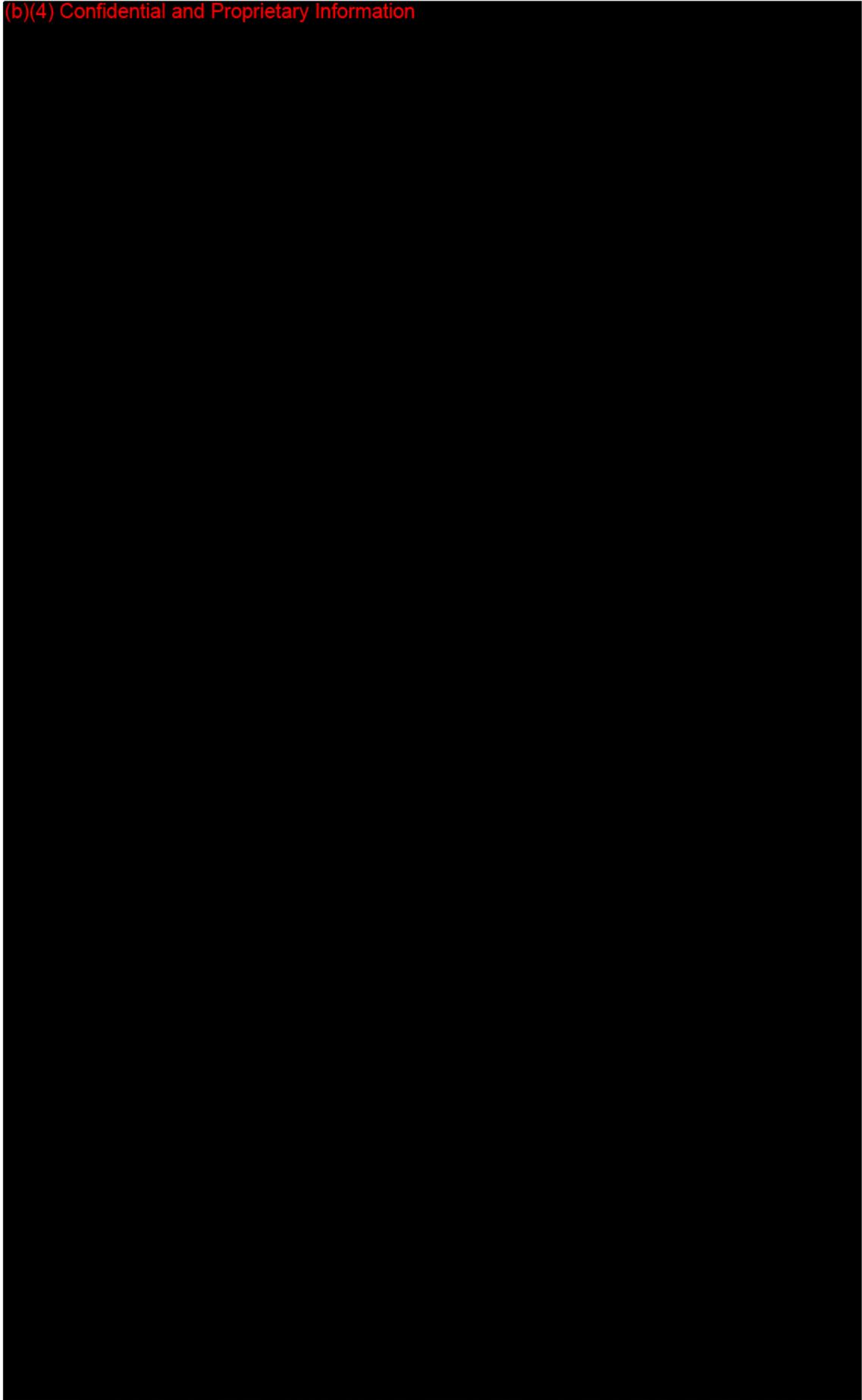
We were satisfied with the additional information provided by Dynatherm to address each of the questions raised by the FDA.

The additional data and information provided by Dynatherm is sufficient to support our recommendation for Substantially Equivalence.

20

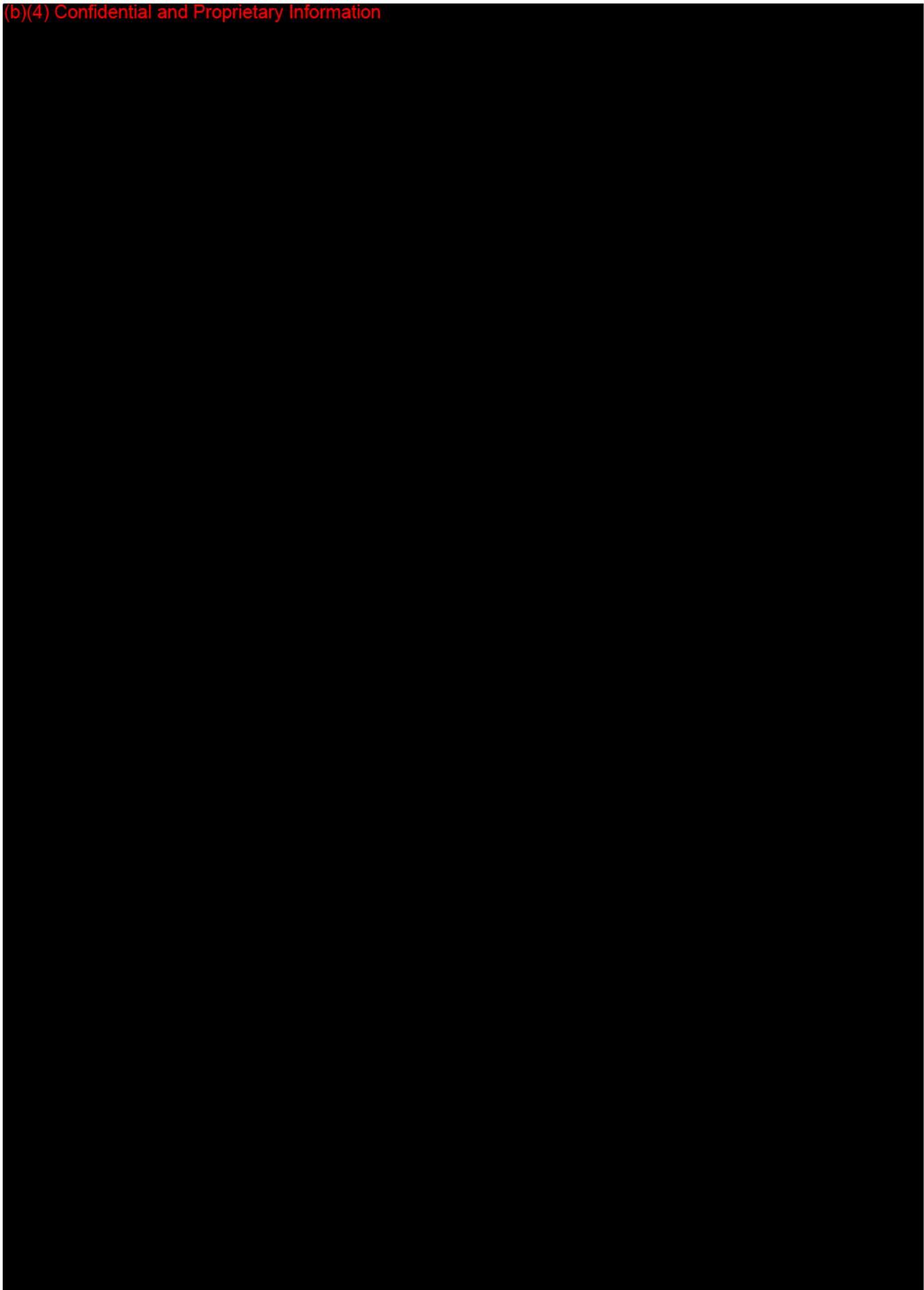
Attachment 11
Page 1/3

(b)(4) Confidential and Proprietary Information



Attachment 11
Page 2/3

(b)(4) Confidential and Proprietary Information



22

Attachment 11
Page 3/3

(b)(4) Confidential and
Proprietary Information





May 24, 2004

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

Attn: Mr. Keith C. Foy.

RE: K040911-510 (k) Premarket Notification VitalHeat™
Dated: April 23 2004
Received: April 26, 2004

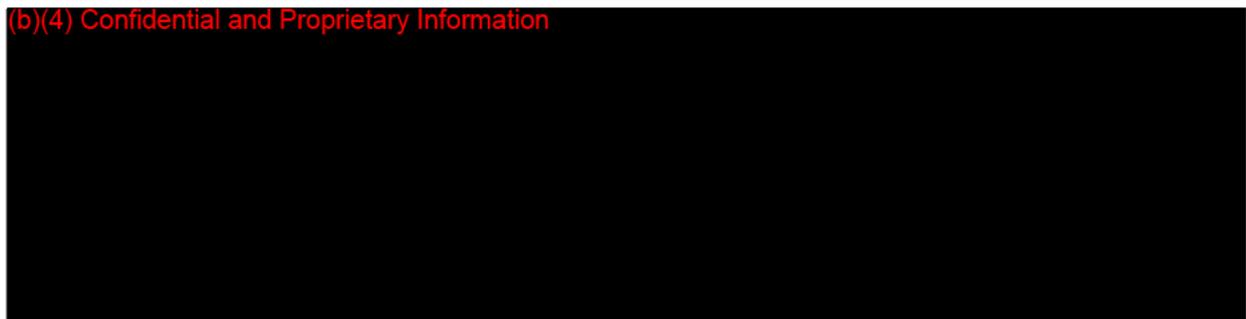
Dear Mr. Foy:

Dynatherm Medical reviewed the Nine (9) questions raised by CDRH concerning the above-referenced Premarket Notification, as you requested and believe that the information provided herein addresses your concerns. FDA questions are in bold letters followed by our response.

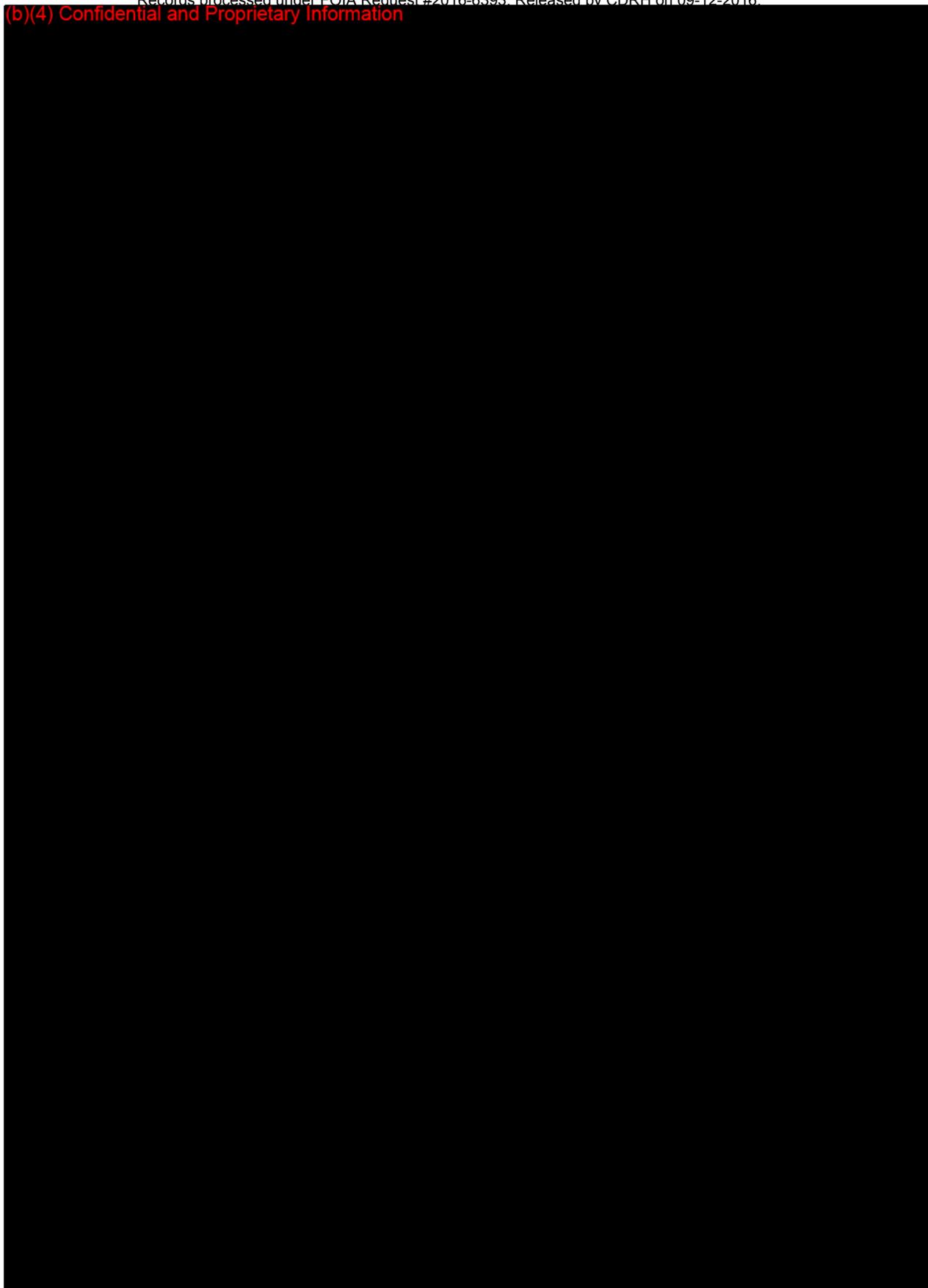
For purposes of clarification, Dynatherm Medical is the new owner of Aquarius Medical, the developer of the Acrotherm™ device (K003368). Dynatherm's VitalHeat™ device is an update of the Acrotherm™ device. Indications for use remain the same, and there are no new safety or efficacy issues.

The VitalHeat™ device makes certain modifications and improvements on the Acrotherm™ device. These are a) The patient interface is improved for better heat exchange, b) The fluid flow rate is increased for better heat exchange, c) The electronics are modernized for better timer control and patient safety, d) the water system is sealed for operator convenience and to reduce risks associated with spillage including potential electrical and slip and fall risk, and e) The device is more compact.

(b)(4) Confidential and Proprietary Information

A large black rectangular redaction box covers the majority of the lower half of the page, obscuring the main body of the letter's content.

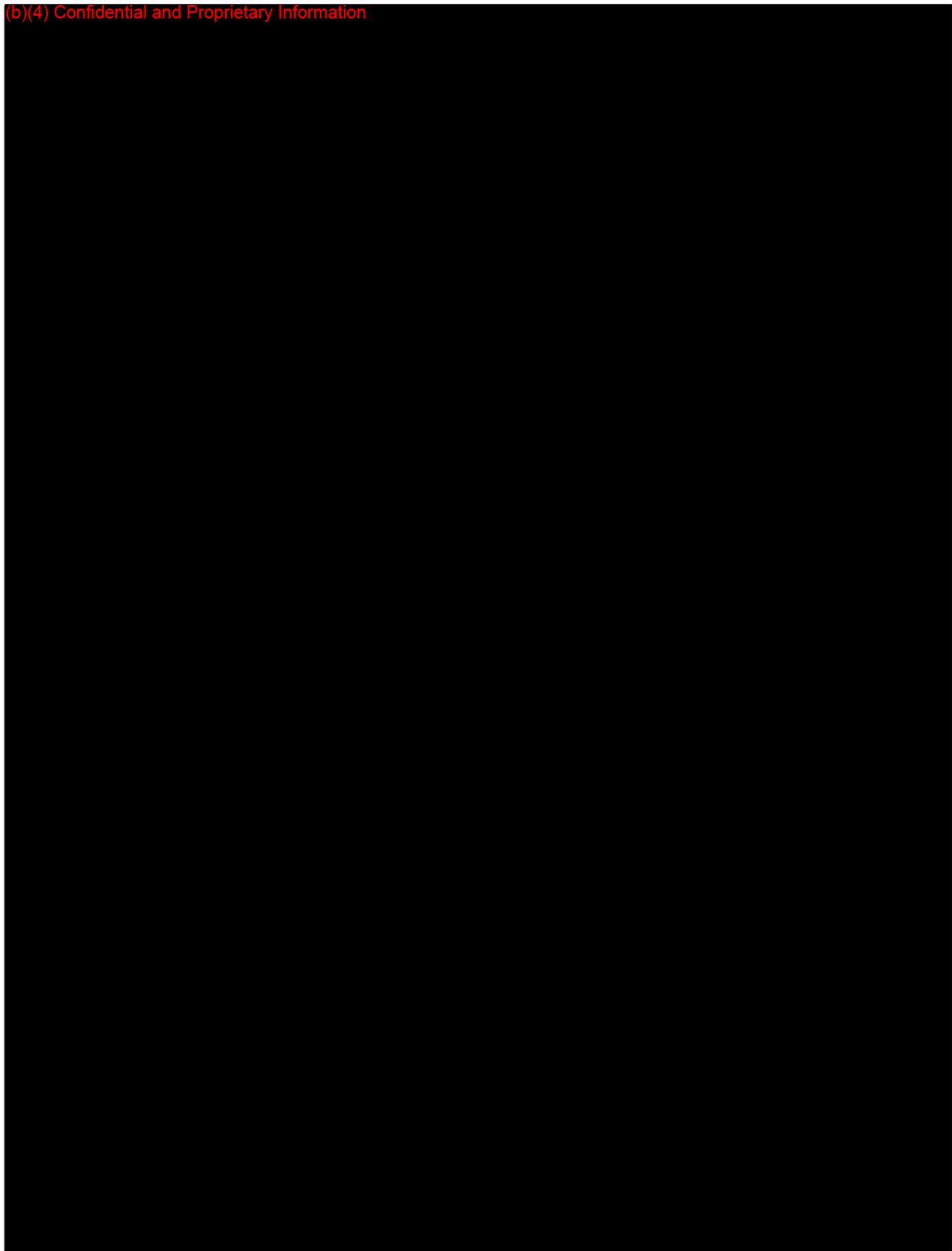
(b)(4) Confidential and Proprietary Information



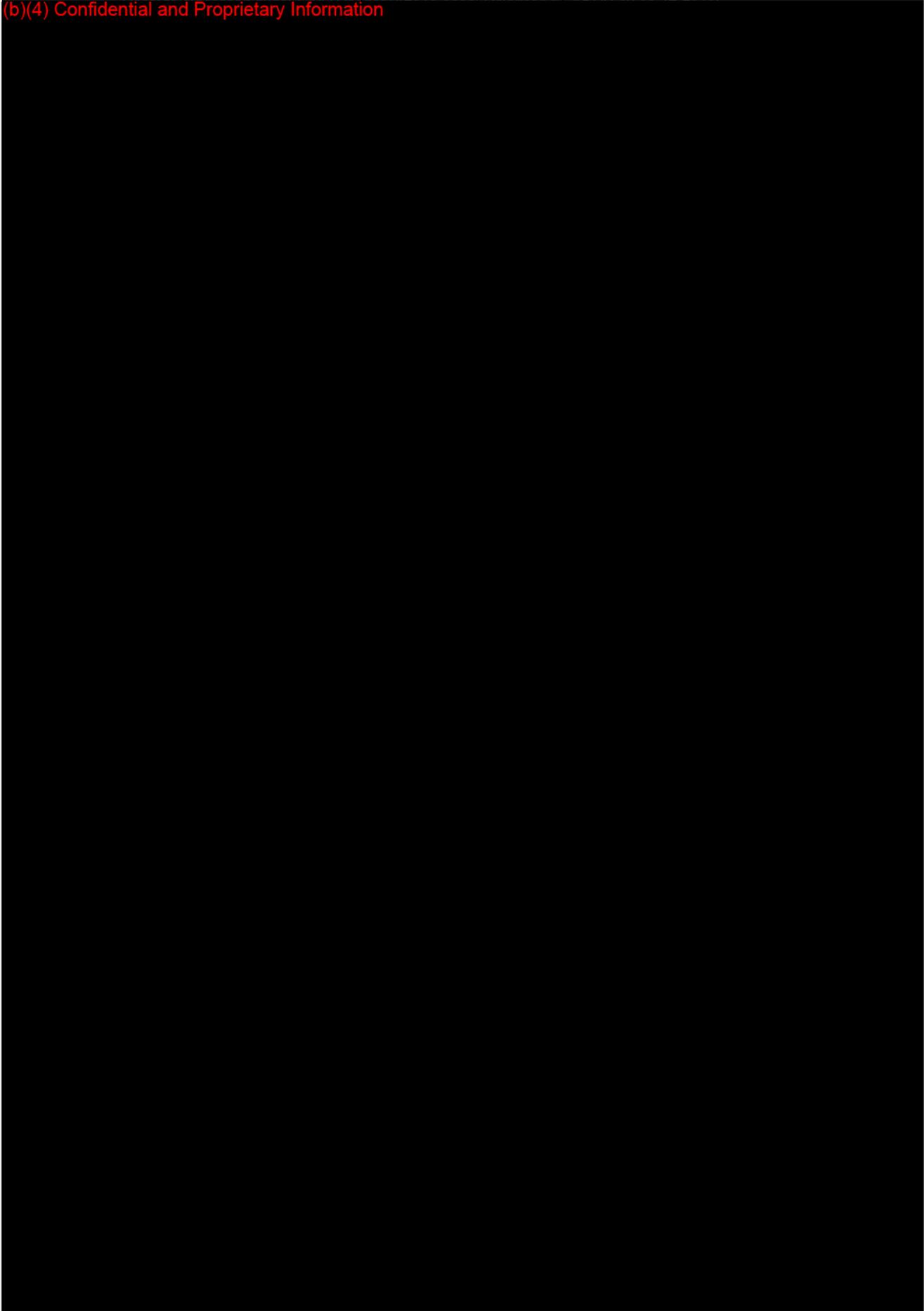
25

26

(b)(4) Confidential and Proprietary Information

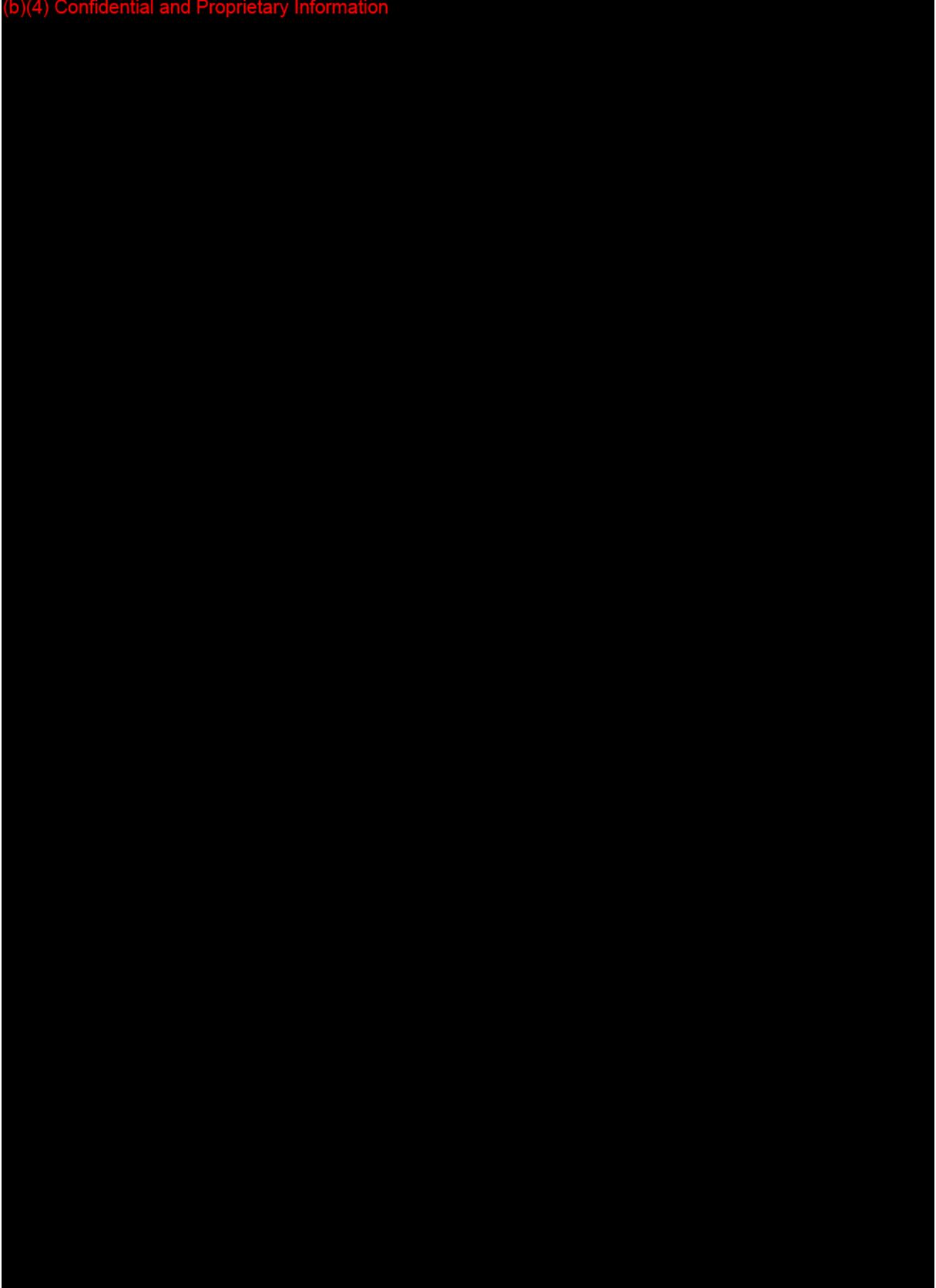


(b)(4) Confidential and Proprietary Information

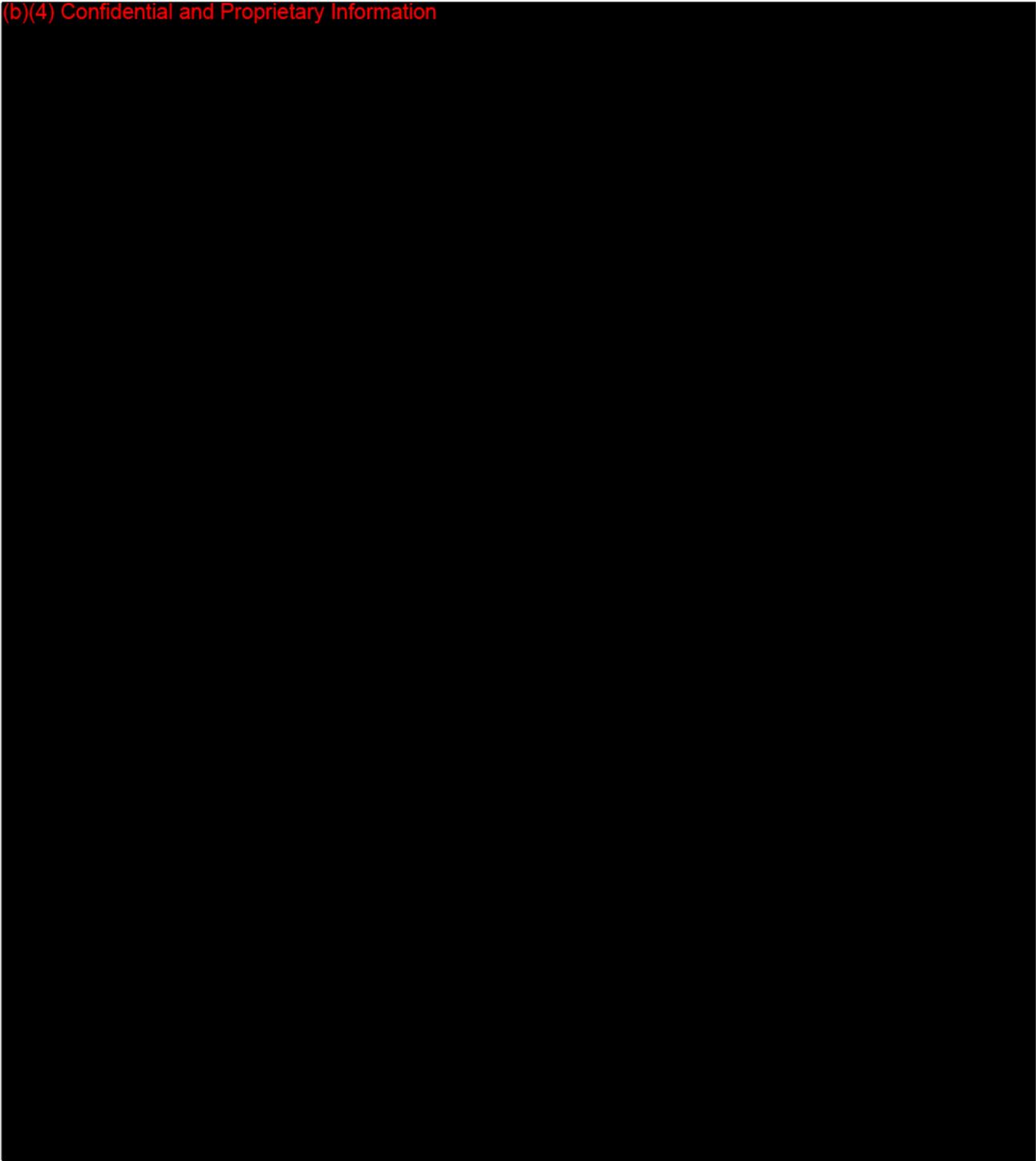


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(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information



Best regards,



Nathan Hamilton
President CEO
Dynatherm Medical, Inc.

APPENDIX A

ILLUSTRATIONS

Page 2 Comparison of Contact Surface Area

Page 3 Front View of Water Tank

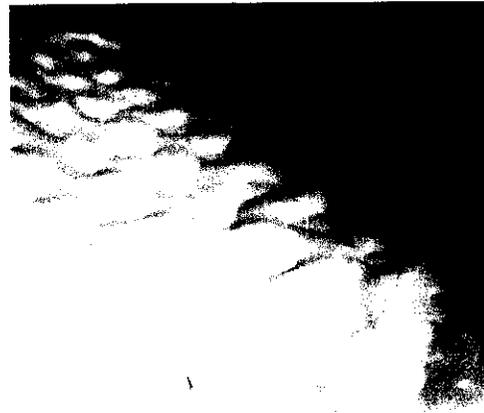
Page 4 Side View of Water Tank

Page 5 Water Heat Exchanger Construction

COMPARISON OF CONTACT SURFACE AREA



VitalHeat™ Palm Surface
20 square inches



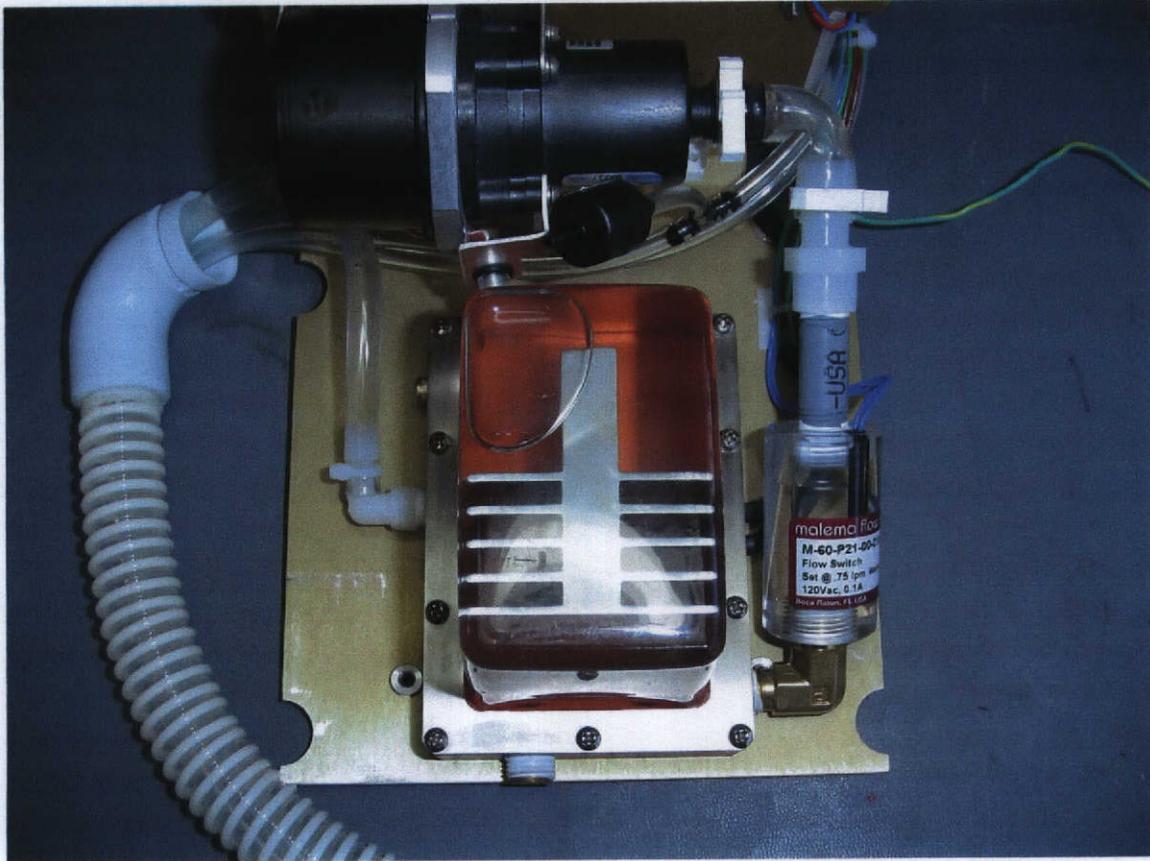
AcroTherm™ "dimpled" heater pad



AcroTherm™ Palm surface
16.34 square inches

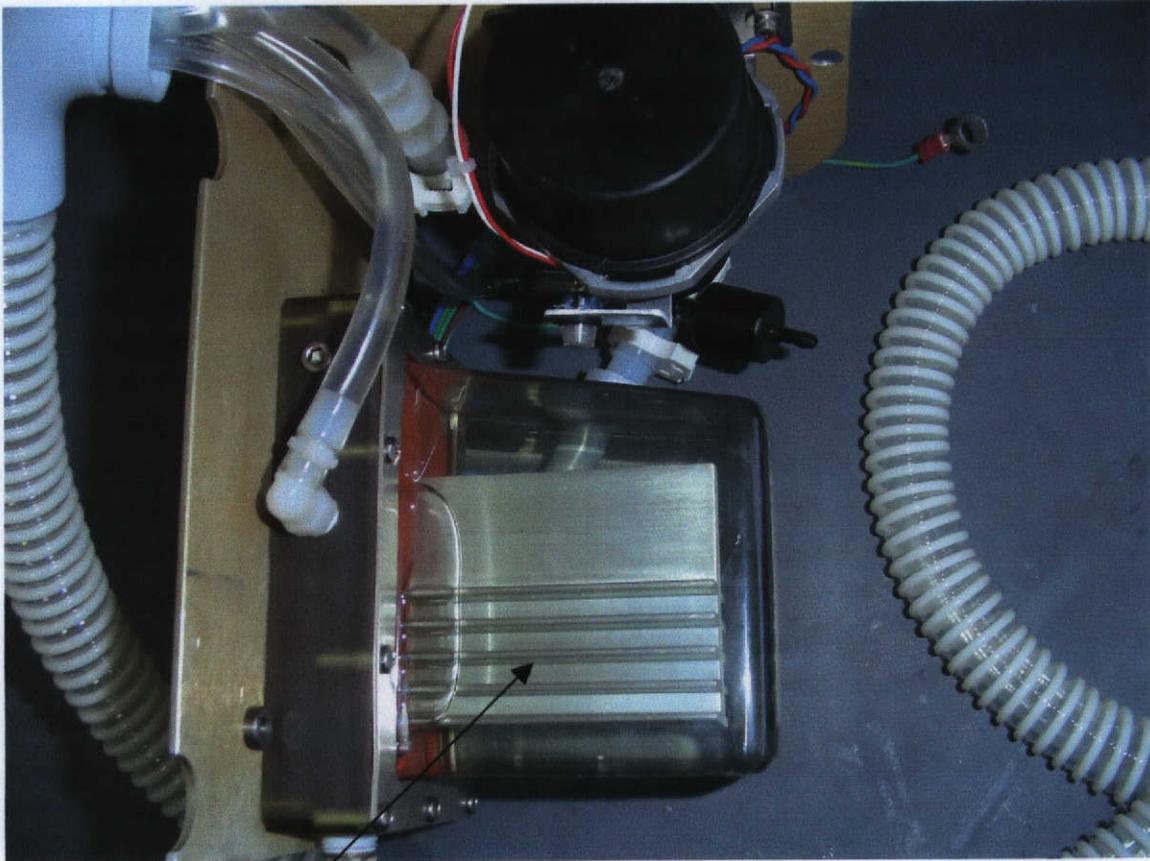


AcroTherm™ Top surface
6.94 square inches



FRONT VIEW OF WATER TANK

Appendix A – Page 3

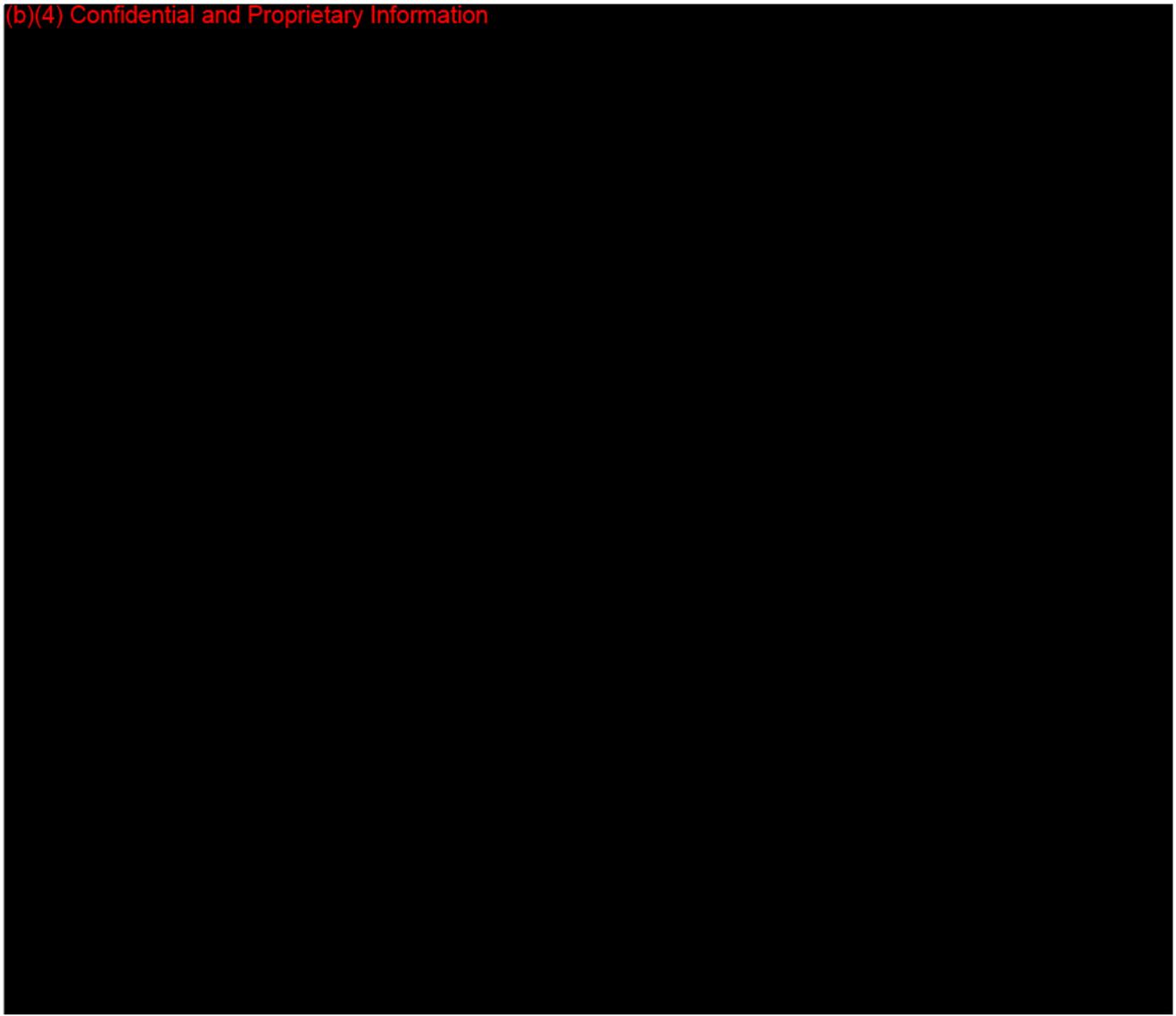


SIDE VIEW OF WATER TANK

Internal Heatsink

Water Heat Exchanger Construction

(b)(4) Confidential and Proprietary Information



Appendix A – Page 5

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APPENDIX B

VitalHeat™ Test Report

VitalHeat™ Test Report

TR 0001

TR 0001 Rev.A
DAR 0020 Effectivity: 05/24/04

Dynatherm Medical
Company Confidential

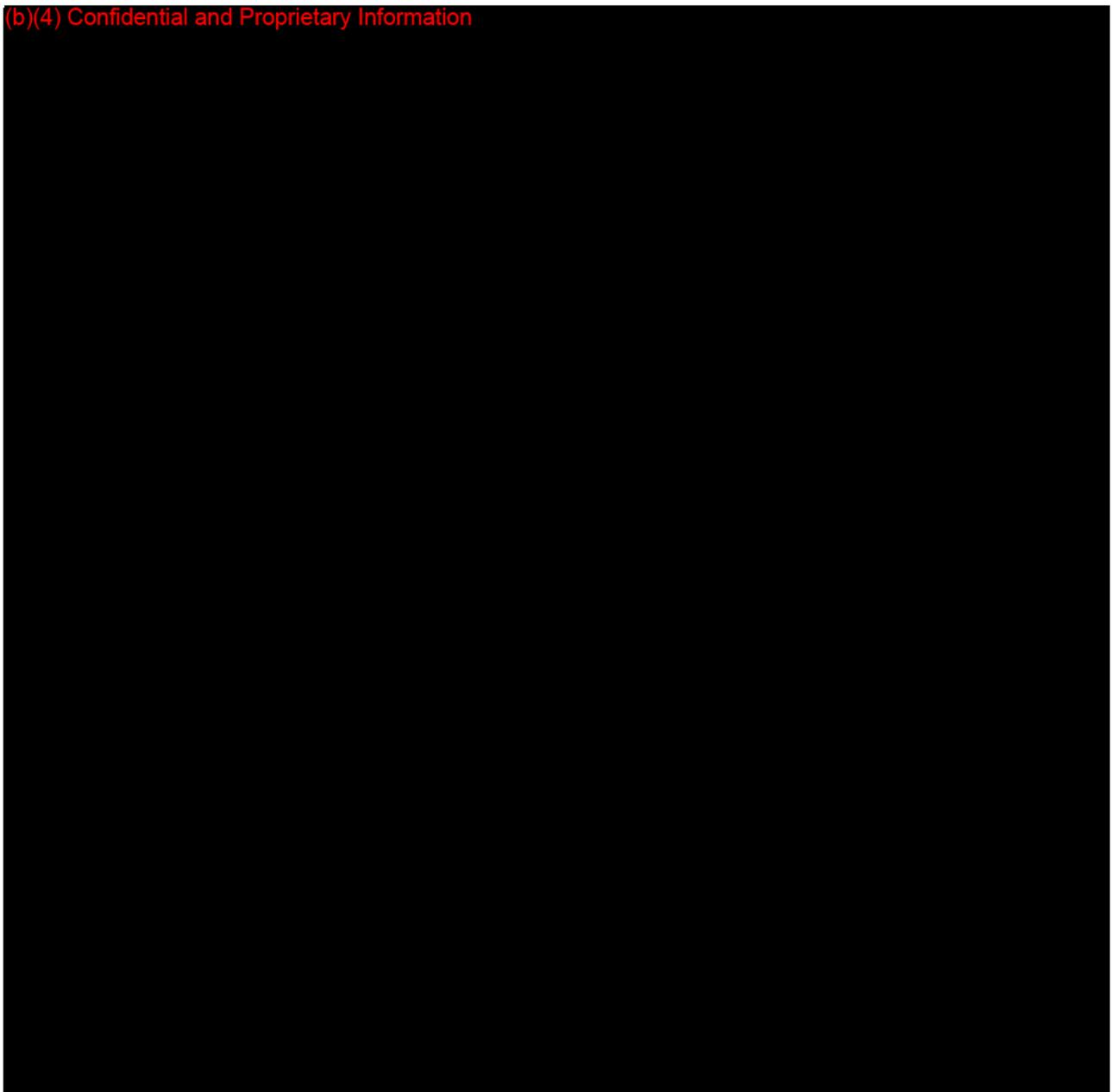
Page 2 of 12

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APPENDIX - C

Clarifications to Dynatherm Medical, Inc. 510 (k) Submittal.

(b)(4) Confidential and Proprietary Information



APPENDIX - D

**Premarket Notification 510(k)
Section 1 – General Information**

VitalHeat™

1.0 General Information

- 1.1 Establishment Name: Dynatherm Medical Corporation
819 Mitten Road
Suite 42
Burlingame, CA 94010
- 1.2 Establishment Number:
- 1.3 Official Correspondent: John R. Kane
- 1.4 Device Name: VitalHeat™
- 1.5 Classification: Class II
- 1.6 Classification Reference: 21 CFR 870.5900
- 1.7 FDA Classification Code: DWJ
- 1.8 Classification Panel: Cardiovascular Panel
- 1.9 Classification Name: Thermal Regulating System
- 1.10 Reason for Submission: Modification to a device cleared under K003368
- 1.11 Predicate Devices: Aquarius Medical Corporation, Inc.
Thermo-STAT – K970367
Cleared December 17, 1997
- Aquarius Medical Corporation
Acro Therm – K003368
Cleared January 19, 2001
- AVACore Technologies, Inc.
Palmo Thermoregulation Interface Accessory
K014210
Cleared May 24, 2002
- 1.12 Performance Standards: None applicable under Section 514
- 1.13 Intended Use: The VitalHeat™ is designed to Non-Invasively Treat hypothermic patients by warming their body ore. This accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.1 Summary of Safety and Effectiveness

Indications for Use:

The VitalHeat™ designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Dynatherm Medical, Inc.

819 Mitten Road, Suite 42

Burlingame, CA 94010

Non-Confidential Summary of Safety and Effectiveness

Page 2 of 3

Patient Population:

For use in patients requiring external thermal management.

Environments of Use:

The device is intended for use throughout healthcare facilities.

Contraindications:

The VitalHeat™ is contraindicated for patients under the age of 18 and for those patients with significant peripheral vascular disease that restricts vasodilatation.

Premarket Notification 510(k)
Section 2 – Certifications and Summaries

VitalHeat™

2.1 Summary of Safety and Effectiveness

Page 3 of 3

510 (k) COMPARATIVE TABLE

COMPANY	DYNATHERM	AMC	AMC	AVAcORE
PRODUCTS	VitalHeat™	ACROTHERM K003368	THERMO-STAT K970367	Palermo Thermoregulation Interface Accessory K014210
Indication for use	Patient Temperature Control and Maintain	Patient Temperature Control and Maintain	Patient Temperature Control	Patient Temperature Control
Intended Environment of use	Healthcare Facilities	Healthcare Facilities	PACU	Healthcare Facilities
Contraindications	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease
Type	Sub Atmospheric Pressure/Water Paddle Disposable Mitt	Sub Atmospheric Pressure/Water Perfusion Pad in Camber	Negative Pressure/ Thermal Pad in Chamber	Sub Atmospheric Pressure/Water Perfusion Pad in Camber
Pressure Device	Yes – Neg.	Yes – Neg.	Yes – Neg.	Yes – Neg.
Sub-Atmospheric Pressure (mmHg)	40 ± 5 mmHg	40 ± 5 mmHg	40 – 60 mmHg	40 – 60 mmHg
Electrical (AC)	Yes	Yes	No	
Temperature Range at Patient interface	≤ 42 ° C	≤ 42 ° C	≤ 45 ° C	≤ 45 ° C
Application Site	Distal Appendage	Distal Appendage	Distal Appendage	Distal Appendage
Control System				
Control Type	Micro - Logic	Micro - Logic	N/A	
Size - Controller	16 x 6 x 6 in.	14 x 6 x 5 in.	N/A	
Weight	15.0 Lbs.	9.30 Lbs.	N/A	
Mobility	Hand-Held IV Pole MTG Table Top	Hand-Held IV Pole MTG Table Top	N/A	
Water Tank	200 ml	400 – 500 ml	N/A	
Flow Rate	> 1000 ml/Min.	< 500 ml/Min.	N/A	
Safety				
High Temperature Alarm	Yes	Yes	No	
Water Level	Yes – Water Flow	Yes	N/A	
Sub-Atmospheric Pressure	Yes LED and Audible	Yes LED and Audible	Yes LED Only	
Timer	Yes	No	No	
Seal	Yes	Yes	N/A	NO

**Premarket Notification 510(k)
Section 2 – Certifications and Summaries**

VitalHeat™

2.3 Indications for Use

510(k) Number: _____ (To be assigned)

Device Name: VitalHeat™

Indications for Use: The VitalHeat™ is designed to non-invasively treat hypothermic patients by warming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **or** **Over-the-Counter Use**
(Per CFR 801.109) _____

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Premarket Notification 510(k)
Section 4 – Device Description

VitalHeat™

Section #12 includes drawings of the VitalHeat™. Below is a summary of the device features

4.2 Summary of Device Features

Summary of Device Features

PRODUCT	VitalHeat™
Intended Use	Patient Temp. Management
Type	Negative Pressure/ Water Heated Aluminum Dome
Pressure Device	Yes-sub-atmospheric
Sub-atmospheric pressure (mmHg)	40±5
Electric (AC)	Yes
Temp. Range at Paddle	42° < ° C
Application Site	Distal Appendage
Disposable Type	Single use Mitt
Control System	
Controller Type	Micro-logic/hardware
Size	14x6x5 in
Weight	15 lb
Mobility	Hand-held
Water Tank	300 – 350 ml
Safety	
High Temperature Alarm	Yes
Water Flow Alarm	Yes
Sub-Atmospheric Pressure Alarm	Yes
Electrical Safety	Yes UL 2601-1 and IEC 601-1-2

4.3 Indications for Use

The VitalHeat™ designed to non-invasively treat hypothermic patients by rewarming their body core. This is accomplished with local application of negative pressure and thermal load (heat) to a distal appendage.

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Premarket Notification 510(k)
Section 5 – Comparison to Predicates

VitalHeat™

5.1 Discussion of the Comparison and Differences

The VitalHeat™ is a modification of a 510(k) cleared thermal regulating system, the AcroTherm™ K003365. The modified device utilizes a circulating water paddle system, similar to the systems of other devices in this classification. **Table 5.01** summarizes the major elements of comparison for the modified device and the two predicate devices.

The VitalHeat™, like the AcroTherm™, applies a combination of heat and sub-atmospheric pressure to a distal limb. Both devices have the limb and heat source enclosed in a mitt. The main difference between the VitalHeat™ and the AcroTherm™ is the patient interface. In the VitalHeat™, heat is supplied by a shaped aluminum dome rather than a dimpled water perfusion pad. Water, the heat transfer fluid, is maintained at a constant temperature within a specified range. The temperature range at the patient interface of both devices are essentially the same. In addition, The VitalHeat™ has a separate control unit and connecting hoses to supply the heated water and sub-atmospheric pressure to the mitt.

The VitalHeat™ system has similar but improved design compared with the predicates. AcroTherm™ used an open water loop system, the water was added to the tank through a removable cap on the control unit. The heated water flowed through the tubing to the warming chamber. Inside the chamber were two (2) dimpled water perfusion pads, in contact to the patient's hand and wrist both top and bottom. The warming mitt was also detachable from the tubing set thru a connector. We found through customer interface that filling the system with water and keeping it clean was difficult.

VitalHeat™ is a closed loop system. Water is added at the factory and unit is shipped to the customer filled. The VitalHeat™ uses the distal appendage as does AcroTherm™ but heat transfer is focused on the palm of the distal appendage, which contains an extremely high concentration of heat transfer capillaries. Heat is transferred to the palm by water circulating through an aluminum paddle. The paddle is shaped to provide maximum hand contact. This design dramatically increases the heat transfer to this critical area compared with the AcroTherm™ type water perfusion pads.

Water Tank 200ML vs. 400 – 500 ML

The Volume of water was reduced in the tank because the system is sealed. The system does not require refilling, thus eliminating the extra water needed to accommodate fluid loss.

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Premarket Notification 510(k)
Section 5.0 Comparison to Predicates

VitalHeat™

5.3 Predicate Information

Table 5.01 Comparative Table

COMPANY	DYNATHERM	AMC	AMC
PRODUCTS	VitalHeat™	ACROTHERM K003368	THERMO-STAT K970367
Intended use	Patient Temperature Control and Maintain	Patient Temperature Control and Maintain	Patient Temperature Control
Intended Environment of use	Healthcare Facilities	Healthcare Facilities	PACU
Contraindications	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease	Patients < 18 years Peripheral Vascular Disease
Type	Sub Atmospheric Pressure/Water Paddle Disposable Mitt	Sub Atmospheric Pressure/Water Perfusion Pad in Chamber	Negative Pressure/ Thermal Pad in Chamber
Pressure Device	Yes – Neg.	Yes – Neg.	Yes – Neg.
Sub-Atmospheric Pressure (mmHg)	40 ± 5 mmHg	40 ± 5 mmHg	40 – 60 mmHg
Electrical (AC)	Yes	Yes	No
Temperature Range at the Paddle	≤ 42 ° C	≤ 45 ° C	≤ 45 ° C
Application Site	Distal Appendage	Distal Appendage	Distal Appendage
Control System			
Control Type	Micro - Logic	Micro - Logic	N/A
Size	16 x 6 x 6 In.	14 x 6 x 5 In.	N/A
Weight	15.0 Lbs.	9.30 Lbs.	N/A
Mobility	Hand-Held IV Pole MTG Table Top	Hand-Held IV Pole MTG Table Top	N/A
Water Tank	200 ml	400 – 500 ml	N/A
Flow Rate	> 1000 ml/Min.	< 500 ml/Min.	N/A
Safety			
High Temperature Alarm	Yes	Yes	No
Water Level	Yes	Yes	N/A
Sub-Atmospheric Pressure	Yes LED and Audible	Yes LED and Audible	Yes LED Only
Timer	Yes	No	No
Seal	No	Yes	N/A

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5.2.2.3 Contamination Containment
 The disposable's design will limit bodily fluids and/or particulates from contaminating the warming mitt.

5.2.2.4 Cost Effective and Disposability
 The cost effectiveness and ease of use of the mitt enables this element to be a single-use only disposable.

5.1.1.1 Universal Seal (one size fits all)
 The unit features a highly compliant wrist seal to accommodate most arm sizes and shapes. This feature aids in providing an easy to use and reliable low-vacuum seal at the arm interface.

5.2.3 Control Unit with paddle

5.2.3.1 Proper Heat and Sub-Atmospheric Pressure
 The unit features proper heat and sub-atmospheric pressure by means of an analog, closed-loop feedback system. This feature ensures the correct heat and sub-atmospheric pressure is supplied for intended performance.

5.2.3.2 Control Unit (front side)
 The control unit features an easy access control panel. The control panel includes the following indicators and warnings:

- ❖ "proper mitt vacuum" / "improper mitt vacuum" indicator lights
- ❖ Run indicator light
- ❖ Temperature indicator lights - "warm up", "treatment temp", "over temp"
- ❖ Audible alarms (85 dB at six feet) – Over-temperature and over vacuum audible alarm

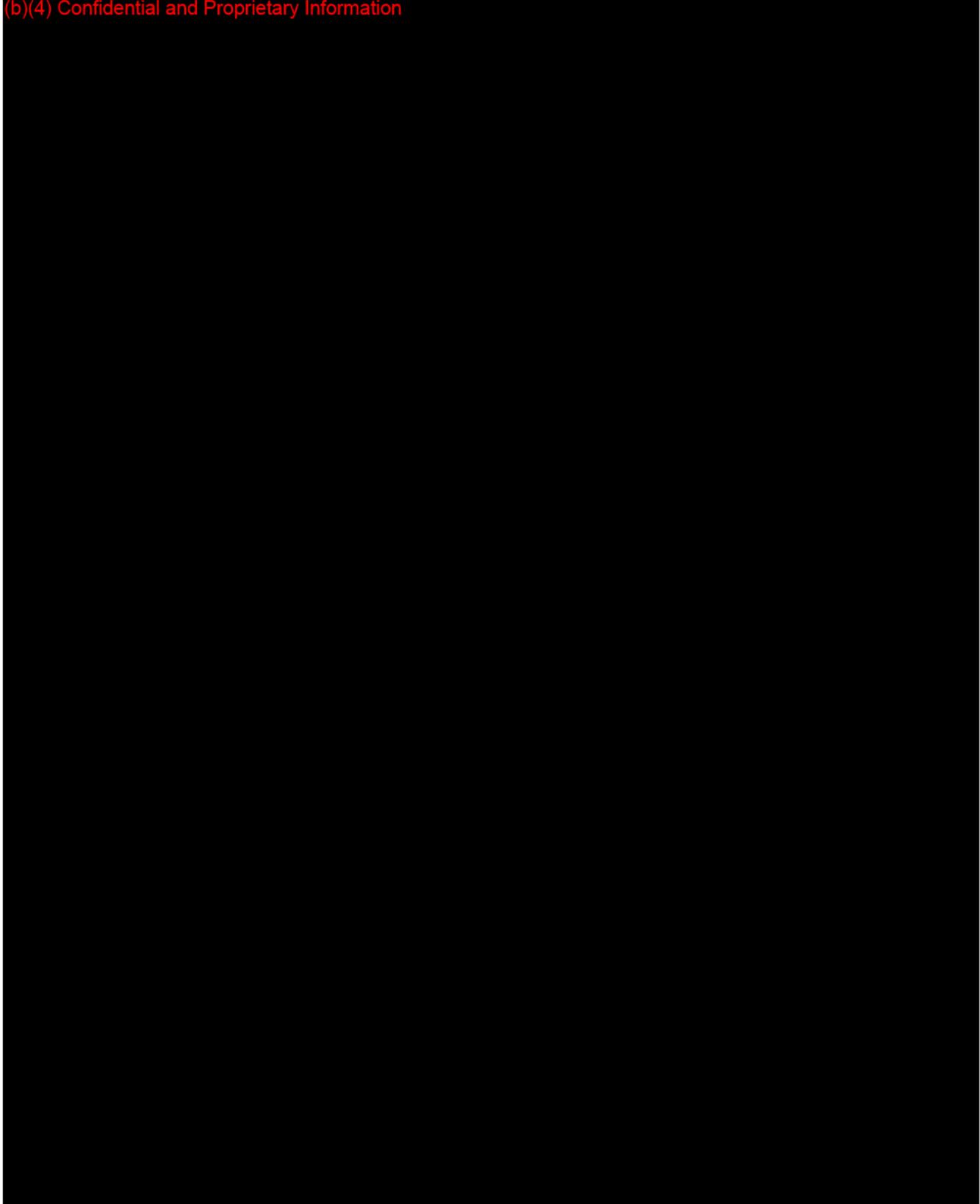
Indicator/warning	Specification at Controller/Reservoir Heat Sink	Specification at Paddle/Patient Interface
Proper mitt vacuum	40 +/- 5 mmHg	40 +/- 5 mmHg
Improper mitt vacuum	< 25 mmHg	< 25 mmHg
Warm up temp	< 35°C	< 35°C
Treatment temp	43 + 0/-2° C	<42°C
Over temp	45°C	42°C
Audible alarm	45°C	42°C
Visual alarm	45°C	42°C

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**Premarket Notification 510(k)
Section 14 Risk Analysis**

VitalHeat™

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(b)(4) Confidential and Proprietary Information

