



K123396

Section 5.0: 510(k) Summary

JAN 10 2013

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

| | |
|-----------------------|---|
| Manufacturer | Thermoplastic Comfort Systems, Inc. |
| Address | 2619 Lime Avenue Signal Hill, CA 90755 |
| Telephone | 562-426-2970 |
| Fax Number | 562-426-5154 |
| Contact at TCS | Marilin Posca President |
| E-mail | marilin@tcsdentalinc.com |

Device Name and Classification

| | |
|--------------------------------|--|
| Trade name/Product Name | i.flex by TCS |
| Common/Usual Name | Dental resin |
| Classification Name | Resin, Denture, Relining, Repairing, Rebasings |
| Classification Panel | Dental |
| Product Code | EBI |
| Regulation Number | 21 CFR 872.3760 |
| Class | II |

Predicate Device

| | |
|----------------------|--|
| Manufacturer | Cosmetic Dental Materials, Inc. (The Myerson Company, Ltd.) |
| Device Name | DuraFlex |
| 510(k) Number | K063626 |

Device Description

i.flex by TCS is an injection moldable, flexible, thermoplastic resin provided with trace amounts of colorant added to produce shades of pink. The dental resin is packaged in individual use cartridges or in bulk.

i.flex by TCS is used for fabricating removable dental prosthetic appliances such as full and partial dentures, occlusal splints and night guards.



Indications for Use

i.flex by TCS is a thermoplastic resin used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

Substantial Equivalence

The i.flex by TCS device is substantially equivalent to the DuraFlex dental resin (K063626).

The claim of substantial equivalence for the i.flex by TCS is based on intended use, technology and performance specifications. Both the i.flex by TCS and the predicate device are composed of a thermoplastic, ethylene propylene copolymer identified by its CAS registration number 9010-79-1. Both devices are supplied in a natural or clear state as well as in shades of pink. Both materials are supplied in cartridges which are heated to allow for the injection molding of the resin for the fabrication of dental prostheses.

Biocompatibility

Biocompatibility testing of the i.flex by TCS material was conducted in accordance with ISO standards to demonstrate the safety of the device.

The following biocompatibility tests were conducted:

1. Cytotoxicity: Agar overlay per ISO 10993-5:2009
2. Cytotoxicity: MEM elution per ISO 10993-5:2009
3. Delayed-type hypersensitivity (sensitization): Magnusson-Klingman Method per ISO 10993-10:2010
4. Irritation: Intracutaneous Toxicity (ISO) per ISO 10993-10:2010
5. Genotoxicity: Ames Test per ISO 10993-3:2009

The test results confirm that the i.flex by TCS device is non-cytotoxic, non-sensitizing, non-irritating and non-mutagenic.

Performance Testing to Recognized Standards

The i.flex by TCS device was tested to the applicable clauses of the recognized consensus standards for dental materials listed below.

1. ANSI/ADA Specification No. 12:2002/ISO 1567:1999 - Denture Base Polymers
2. ANSI/ADA Specification No. 80:2001/ISO 7491:2000 - Dental Materials – Determination of Color Stability

The study results demonstrate that the i.flex by TCS meets the performance criteria specified in the recognized standards cited or for the performance of the predicate device, DuraFlex, confirming the substantial equivalence of the i.flex by TCS to the predicate device.



Summary of Performance Testing – Conclusion

The results of all testing demonstrate that the i.flex by TCS device does not raise any new significant issues of safety, effectiveness or performance of the device when compared to the existing predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

January 10, 2013

Ms. Marilyn Posca
President
Thermoplastic Comfort Systems, Incorporated
2619 Lime Avenue
SIGNAL HILL CA 90755

Re: K123396
Trade/Device Name: I.Flex by TCS
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasement Resin
Regulatory Class: II
Product Codes: EBI, MQC
Dated: November 2, 2012
Received: November 5, 2012

Dear Ms. Posca:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Page 2 – Ms. Posca

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

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

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

Sincerely yours,


Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



510(k) Number (if known): K123396

Device Name: i.flex by TCS

Indications For Use:

i.flex by TCS is a thermoplastic resin used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

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)

Susan Runner DDS, MA 2013.01.09
14:27:21 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: k123396

K123396 V.1



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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page
 [THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K123396

For Office of Compliance Contact Information:

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

For Office of Surveillance and Biometrics Contact Information:

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

| Digital Signature Concurrence Table | |
|--|--|
| Reviewer Sign-Off | Michael E. Adjodha -S 2013.01.09 10:37:12 -05'00' |
| Branch Chief Sign-Off | Susan Runner DDS, MA 2013.01.10 10:47:54 -05'00' |
| Division Sign-Off | Kwame O. Ulmer 2013.01.10 10:14:32 -05'00' |

Template Name: K1(A) – SE after 1996

Template History:

| Date of Update | By | Description of Update |
|----------------|-------------------|---|
| 7/27/09 | Brandi Stuart | Added Updates to Boiler Table |
| 8/7/09 | Brandi Stuart | Updated HFZ Table |
| 1/11/10 | Diane Garcia | Liability/Warranty sentence added at bottom of 1 st page |
| 10/4/11 | M. McCabe Janicki | Removed IFU sheet and placed in Forms |
| 9/25/12 | Edwena Jones | Added digital signature format |



510(k) Number (if known): K123396

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(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
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Susan Runner DDS, MA 2013.01.09
14:27:21 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: k123396

* * * COMMUNICATION RESULT REPORT (JAN. 11. 2013 8:52AM) * * *

FAX HEADER 1:
FAX HEADER 2:

| TRANSMITTED/STORED : F. MODE | JAN. 11. 2013 8:44AM OPTION | ADDRESS | RESULT | PAGE |
|---------------------------------|--------------------------------|--------------|---------|------|
| 2417 MEMORY TX | | 915264265154 | E-3) 3) | 0/3 |

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

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

January 10, 2013

Ms. Marilyn Posca
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2619 Lime Avenue
SIGNAL HILL CA 90755

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Michael E. Adyodha
Subject: 510(k) Number K123396
To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

| Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.): | | YES | NO |
|---|--------------------------------------|-----|----|
| Indications for Use Page | Attach IFU | ✓ | |
| 510(k) Summary / 510(k) Statement | Attach Summary | ✓ | |
| Truthful and Accurate Statement. | Must be present for a Final Decision | ✓ | |
| Is the device Class III? | | | ✓ |
| If yes, does firm include Class III Summary? | Must be present for a Final Decision | | |
| Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf) | | ✓ | |
| Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC) | | | ✓ |
| Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html) | | | ✓ |
| Is this device intended for pediatric use only? | | | ✓ |
| Is this a prescription device? (If both prescription & OTC, check both boxes.) | | ✓ | |
| Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? | | | ✓ |
| Is clinical data necessary to support the review of this 510(k)? | | | ✓ |
| For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was | | | ✓ |

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age <= 21

Neonate/Newborn (Birth to 28 days)

Infant (29 days - < 2 years old)

Child (2 years - < 12 years old)

Adolescent (12 years - < 18 years old)

Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC.

✓
✓
✓
✓
✓
✓
✓
✓

Regulation Number 21 CFR Class* II Product Code EBI
872.3760

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

MQC

Review:

Susan Runner
(Branch Chief)

DEA
(Branch Code)

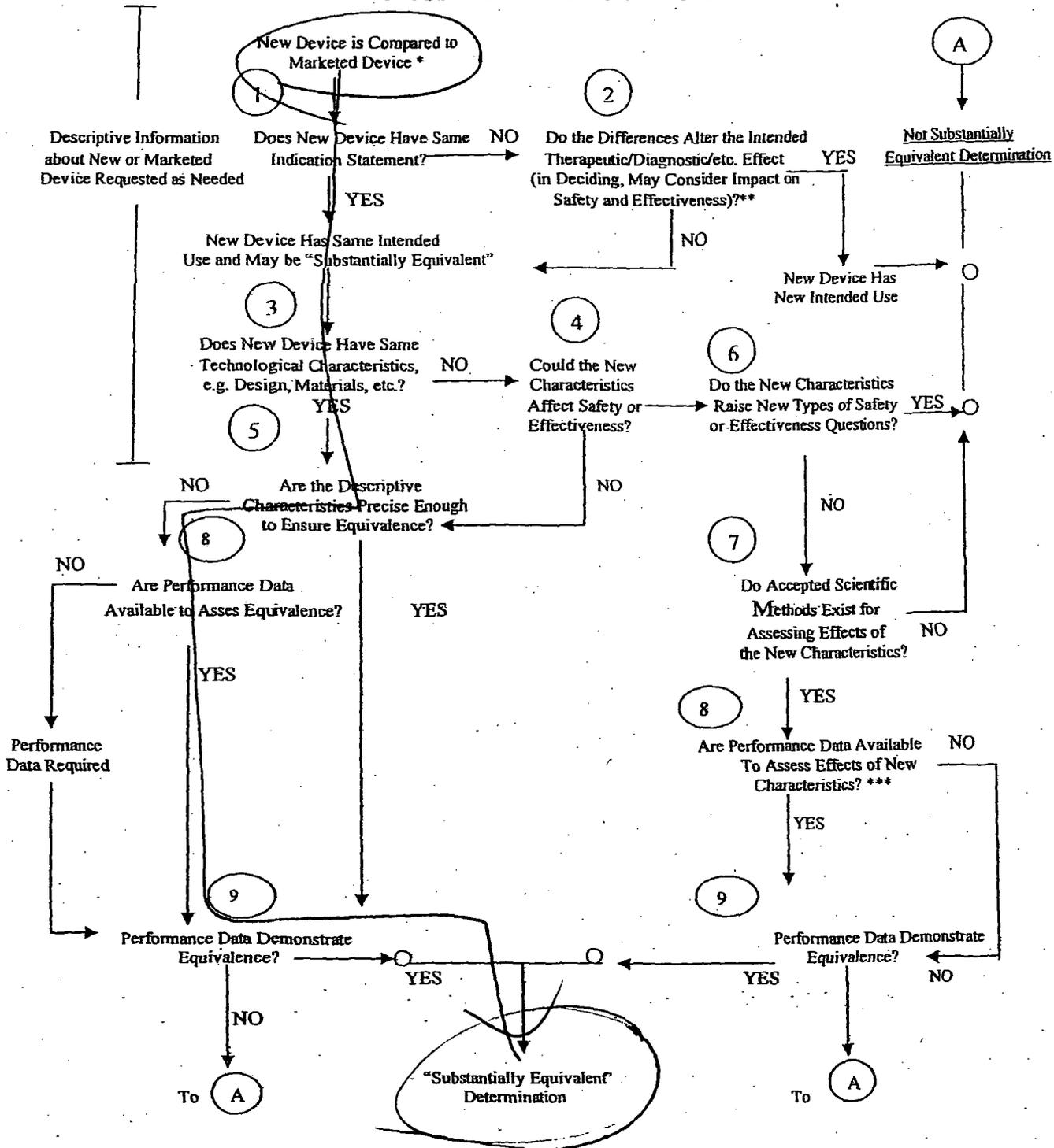
1/10/13
(Date)

Final Review:

[Signature]
(Division Director)

1/10/13
(Date)

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 may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
 CDRH/Office of Device Evaluation
 10903 New Hampshire Avenue, Bldg. 66
 Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
 Traditional/Abbreviated**

K123396

Date: 08 January 2013
To: The Record
From: Michael E. Adjodha, MChE, Chemical Engineer
Office/Div/Br: ODE/DAGRID/DEDB
510(k) Submitter: Thermoplastic Comfort Systems, Inc., Tokyo, JAPAN
Device Name: *I.Flex by TCS*
Contact: Ms. Marilyn Posca
Phone: 562-426-2970
Fax: 562-426-5154
Email: marilin@tcsdentalinc.com

Purpose and Submission Summary

The 510(k) submitter would like to introduce *I.Flex by TCS* into U.S. interstate commerce.

I.Flex by TCS is indicated for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

I.Flex by TCS is substantially equivalent (SE) to legally marketed denture resins because the information submitted by Thermoplastic Comfort Systems, Inc., demonstrates that the device has the same indication and technological characteristics as legally marketed denture resins.

Administrative Requirements

| | Yes | No | N/A |
|--|-----|----|-----|
| Indications for Use page (Indicate if: <u>Prescription</u> or OTC) | X | | |
| Truthful and Accuracy Statement | X | | |
| <u>510(k) Summary</u> or 510(k) Statement | X | | |
| Standards Form | X | | |

Indications for Use

I.Flex by TCS is indicated for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

The indications for use of *I.Flex by TCS* do not differ from that of legally marketed denture resins.

Device Description/Materials

| | Yes | No | N/A |
|---|-----|----|-----|
| Is the device life-supporting or life sustaining? | | X | |
| Is the device an implant (implanted longer than 30 days)? | | X | |
| Does the device design use software? | | X | |
| Is the device sterile? | | X | |
| Is the device reusable (not reprocessed single use)? If so, are "cleaning" instructions included for the end user? | | X | |

The purpose of this 510(K) is to introduce a product to the U.S. market. No changes in intended use or technology are introduced.

(b)(4)

I.Flex by TCS achieves its intended function by providing a thermoplastic resin that can be molded to a desired form for the fabrication of partial or full removable dentures, occlusal splints, and night guards.

The formulation of *I.Flex by TCS* is composed of (b)(4)
(b)(4)

The technical and performance specifications of a representative sample of *I.Flex by TCS* include the following:

| Physical Property | <i>I.Flex by TCS</i> |
|-------------------|----------------------|
| (b)(4) | (b)(4) |

Contact History/ Deficiencies

The reviewer contacted the submitter by an email on November 14, 2012, to request certain administrative items that were identified in the RTA checklist. The submitter responded to these requests by an email on November 15, 2012. The submitter's responses adequately address the reviewer's concerns.

Proposed Labeling

The proposed labeling of *I.Flex by TCS* has been provided which includes, indications, warnings, and instructions for use. The directions for use are adequate for this device, which is intended for use only by professionals trained in the art of denture fabrication.

Sterilization/Shelf Life/Reuse:

I.Flex by TCS will be provided non-sterile and is not intended to be sterilized before use. The device, as a thermoplastic, has no setting components and has no estimated shelf life.

Biocompatibility

The composition of *I.Flex by TCS* is based on a (b)(4). This material has been used in legally marketed devices, i.e., *DuraFlex (K063626)* of *The Myerson Company, Ltd.* Biocompatibility testing is not required for *I.Flex*; nevertheless, the submitter conducted the following tests, in accordance with ISO 10933, in order to verify the biocompatibility of this formulation:

| Test | Method | Standard | Result |
|---------------|--|--------------|--------|
| Cytotoxicity | Agar overlay | 10993-5 | (b)(4) |
| Cytotoxicity | MEM elution | ISO 10993-5 | |
| Sensitization | Guinea pig maximization; test sample extracted in saline and cottonseed oil and injected in Guinea pigs. | ISO 10993-10 | |
| Irritation | Intracutaneous toxicity; test sample extracted in saline and cottonseed oil and injected intracutaneously in rabbits | ISO 10993-10 | |
| Genotoxicity | Ames reverse mutation assay | ISO 10993-3 | |

The testing demonstrates that *I.Flex by TCS* presents no new toxicity risks and should be biocompatible for its intended use.

Software

I.Flex by TCS contains no software. Software validation is not applicable.

Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

I.Flex by TCS is not an electrical device and has no moving parts. Therefore, mechanical safety, electrical safety, EMC, and thermal safety are not applicable.

Performance Testing – Bench

Engineering performance test results are provided in Device Description/Formulation section.

Performance Testing – Animal

Animal test results were not provided for *I.Flex by TCS*, neither are they considered necessary for an established formulation/design of this type.

Performance Testing – Clinical

Human test results were not provided for *I.Flex by TCS*, neither are they considered necessary for an established formulation/design of this type.

Device Comparison

Predicate Device: *DuraFlex (K063626)* of The Myerson Company, Ltd.

| Physical Property | <i>I.Flex by TCS</i> | <i>DuraFlex (K063626)</i> |
|---------------------------------------|---|---|
| Intended Use | Indicated for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards | Used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards. |
| Material of Composition | <div style="font-size: 2em; font-weight: bold;">(b)(4)</div> <div style="font-size: 2em; font-weight: bold;">(b)(4)</div> | |
| Ultimate Flexural Strength (MPa) | | |
| Flexural Modulus (GPa) | | |
| Water Sorption | | |
| Water Solubility(µg/mm ³) | | |

I.Flex by TCS is similar in intended use, (b)(4) formulation, and physical properties to legally marketed, flexible denture resins, *DuraFlex (K063626)* of *The Myerson Company, Ltd* in particular. The difference in *I.Flex by TCS* lies in the particular selection and relative percentages of its components, all of which are commonly found in denture base resins. Biocompatibility testing has confirmed that this formulation does not introduce any new toxicity concerns. *I.Flex by TCS* is a minor reconfiguration of a legally marketed denture base resin.

The physical properties of *I.Flex by TCS* are equivalent to those of predicate, flexible denture base resins and are sufficient for its use.

No new technological characteristics have been introduced in *I.Flex by TCS* that could affect the safety or effectiveness of this device, as compared to the generic class of denture resin devices.

Substantial Equivalence Discussion¹

| | Yes | No |
|--|----------------|--|
| 1. Same Indication Statement? | X | If YES = Go To 3 |
| 2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness? | | If YES = Stop NSE |
| 3. Same Technological Characteristics? | X | If YES = Go To 5 |
| 4. Could The New Characteristics Affect Safety Or Effectiveness? | | If YES = Go To 6 |
| 5. Descriptive Characteristics Precise Enough? | | X ² If NO = Go To 8 If YES = Stop SE |
| 6. New Types Of Safety Or Effectiveness Questions? | | If YES = Stop NSE |
| 7. Accepted Scientific Methods Exist? | | If NO = Stop NSE |
| 8. Performance Data Available? | X | If NO = Request Data |
| 9. Data Demonstrate Equivalence? | X ³ | Final Decision: SE |

¹ Note: See http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

² No. Engineering performance data needed.

³ Yes. Engineering performance is equivalent to legally marketed denture base resins.

Recommendation

I.Flex by TCS is substantially equivalent to legally marketed denture resins under the following classification regulation:

Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Repairing Resin
Regulatory Class: Class II
Product Codes: EBI and MQC

Michael E. Adjodha -S
2013.01.08 14:20:51 -05'00'

Michael E. Adjodha, MChE,
Reviewer

2013.01.08
Susan Runner DDS, MA 14:37:47
-05'00'

Susan Runner, DDS, MA
Branch Chief

Adjodha, Michael E

From: Marilyn Posca <marilin@tcsdentalinc.com>
Date: Thursday, November 15, 2012 5:24 PM
Subject: Re: RTA for IFlex (K123396)
Attachments: iflex label.pdf

Re: 510(k) K123396

Dear Mr. Michael Adjodha,

As requested, we have reviewed the checklist that you have provided and have addressed all of the elements identified as missing or inconsistent in our 510(k) submission. The additional information requested is presented below.

Please let us know if you request additional information or clarification so that you may continue with your substantive interactive review.

Sincerely,

Marilyn Posca

Item No. 10: There have been no prior submissions made for this device.

Item No. 11 and No. 31: Information on the complete chemical composition of the device is provided below.

The i.flex by TCS device is a thermoplastic (b)(4)
(b)(4) The colorant is listed in 21 CFR 178.3297(e) as an FDA approved color additive for polymers for use in food production and packaging.

(b)(4)

| Component | Chemical Name | CAS No. | Concentration |
|-----------|---------------|---------|---------------|
|-----------|---------------|---------|---------------|

(b)(4)

(b)(4)

Item No. 18: Proposed Labeling – Directions for use

The i.flex by TCS device is exempt from adequate Directions for Use based upon 21 CFR 801.122 – Medical devices for processing, repacking or manufacturing. The device is intended for use for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards. As such it is a device that is intended for processing in the manufacture of another device. The labeling for the marketed device will include the statement “Caution: For manufacturing, processing, or repacking.”

Item No. 32: Contact Classification

The i.flex by TCS material is a patient-contacting device with contact with the mucosal membranes of the mouth with multiple contact periods which cumulatively exceeds 30 days.

Attachment: Revised Label

Marilyn Posca
Thermoplastic Comfort Systems Inc.
2619 Lime Ave.
Menlo Park, CA 94025
650-426-2970/ 866-426-2970
562-426-5154 Fax
www.tcsdentalinc.com

View Our Upcoming Training Course visit our website

TCS, Inc. - Confidential Communication

The information contained in this e-mail is confidential and may be subject to legal professional privilege. It is intended solely for the addressee. If you receive this e-mail by mistake please promptly inform us by reply e-mail and then delete the e-mail and destroy any printed copy. You must not disclose or use in any way the information in the e-mail. Thank you very much for your cooperation.

On Wed, Nov 14, 2012 at 4:41 AM, Adjodha, Michael E <Michael.Adjodha@fda.hhs.gov> wrote:

Dear Ms. Posca,

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K123396. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness.

Our Refuse to Accept (RTA) policy has not yet been implemented. Therefore, during this transitional phase, we have begun our substantive review of your 510(k) submission, and we are requesting the missing information interactively.

Please refer to the attached checklist and e-mail your response to me referencing the 510(k) number K123396 by November 21, 2012. Your response should address all of the elements identified as missing or inconsistent in the attached checklist. Failure to provide the requested information by November 21 may result in your submission being placed on hold.

Upon receipt of the requested information, FDA may have additional requests for information.

Please be advised that once our RTA policy is implemented, if your 510(k) submission does not meet the criteria established for administrative completeness, your file will not be accepted and we will not begin our substantive review until you submit the missing elements and your submission is accepted. Refer to the draft guidance document for information.

Should you have questions about this email, you may contact me, the lead reviewer assigned to your 510(k) submission.

Sincerely,

Michael

Michael E. Adjodha, MChE
Chemical Engineer
Food and Drug Administration
Center for Devices and Radiological Health
Dental Devices Branch
10903 New Hampshire Avenue
WO66-2606
Silver Spring, MD 20993-0002
E-mail: michael.adjodha@fda.hhs.gov
Phone: [301-796-6276](tel:301-796-6276)

iFlex
by tcs.

Thermoplastic Dental Resin
For the Manufacturer of Removable Dental Prosthetics

LOT _____

SIZE

Small Nt. Wt: ~0.28 oz. (~7.9g) each tube

Medium Nt. Wt: ~0.63 oz. (~17.5g) each tube

Large Nt. Wt: ~0.90 oz. (~25.5g) each tube

CAUTION: For Manufacturing or Processing

MADE IN THE USA  **EC REP** MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

SHADE

tcs® 1 Light Pink

tcs® 2 Standard Pink

tcs® 3 Light/Dark Pink

tcs® 4 Dark Pink

tcs® Natural

Other _____

CE
0470

EN Thermoplastic Dental Resin: *For the Manufacture of Removable Dental Prosthetics*

Indicated Use: Removable partial dentures, removable full dentures, occlusal splints, nightguards.
Not Suitable For: Fixed restorations, unilaterals.

Warnings: For Professional use only. Use eye protection and heat-resistant gloves during injection process, use proper ventilation, vacuum system and mask during finishing stage.

Instructions:

1. Once removed from sealed plastic bag, store cartridges in a dry place and at 90°F to 100°F (32°C to 38°C) at all times or at least 12 hours prior to use.
2. Melt I.flex according to manufacturer's instructions for type of furnace being utilized. Approximately 550°F (288°C) for 11 minutes.
3. Proceed using standard methods and practices for thermoplastics. (See TCS Injection System Operators Manual for detailed instructions)

Available Shades:
Lt. Pink, St. Pink, Light-Dark Pink,
Dark Pink, Natural

Available Sizes:
Small, Medium, Large



Thermoplastic Comfort Systems, Inc.
2619 Lime Ave. Signal Hill, CA 90755 U.S.A.
www.tcsdentalinc.com / www.facebook.com/tcsdental

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**Acceptance Checklist
for Traditional 510(k)s**

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: K123396

Date Received: 11/6/2012

Device Name: I.Flex

Lead Reviewer Name: Michael E. Adjodha Branch: DEDB Division: DAGRID Office: ODE

| Preliminary Questions | | |
|---|------------|-----------|
| Answers in the shaded blocks indicate consultation with Center advisor is needed. | Yes | No |
| <p>1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?</p> <p>If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."</p> | X | |
| Comments: | | |
| <p>2. Is the application with the appropriate Center?</p> <p>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If application should not be reviewed by your Center mark "No."</p> | X | |
| Comments: | | |
| <p>3. Is a 510(k) the appropriate regulatory submission?</p> <p>If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."</p> | X | |

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| | | |
|--|--|---|
| Comments: | | |
| <p>4. Is there a pending PMA for the same device with the same indications for use?</p> <p>If there is a pending PMA for the same device, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.</p> | | X |
| Comments: | | |
| <p>5. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</p> <p>If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.</p> | | X |

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter. If the answer to 3 is no, the lead reviewer should consult division management and other Center resources to determine the appropriate action.

If the answer to 4 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

If the answer to 5 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

| <u>Organizational Elements</u> | | |
|---|-----|----|
| <i>Failure to include these items alone generally should not result in an RTA designation</i> | | |
| | Yes | No |
| a. Submission contains Table of Contents | X | |
| b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.) | X | |
| c. All pages of the submission are numbered <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i> | X | |
| d. Type of 510(k) is identified– traditional, abbreviated, or special <i>If type of 510(k) is not designated, review as a traditional</i> | X | |
| Comments: | | |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | |
|---|---|---|--------------------------|--------------------------|
| Submission should be designated RTA if not addressed | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | |
| | | <ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A |
| | | | | |
| A. | Administrative | | | |
| 1. | All content used to support the submission is written in English (including translations of test reports, literature articles, etc.) | | X | <input type="checkbox"/> |
| | Comments: | | | |
| 2. | 510(k) cover letter that identifies: | | <input type="checkbox"/> | <input type="checkbox"/> |
| | a. | Device trade name or proprietary name | X | <input type="checkbox"/> |
| | b. | Device common name | X | <input type="checkbox"/> |
| | c. | Device class and panel | X | <input type="checkbox"/> |
| | Comments: | | | |
| 3. | Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109) <i>Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.</i> | | X | <input type="checkbox"/> |
| | Comments: | | | |
| 4. | Submission contains 510(k) Summary or 510(k) Statement <i>Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.</i> | | X | <input type="checkbox"/> |
| | a. | Summary contains all elements per 21 CFR 807.92 <i>See also <u>510(k) Summary Checklist</u></i> | X | <input type="checkbox"/> |
| | b. | Statement contains all elements per 21 CFR 807.93 | <input type="checkbox"/> | X |
| | Comments: | | | |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | | |
|---|--|--|--------------------------|--------------------------|--------------------------|
| Submission should be designated RTA if not addressed | | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | | |
| | <ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A | No | |
| 5. | Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended <u>format</u></i> | X | | <input type="checkbox"/> | |
| | Comments: | | | | |
| 6. | Submission contains Class III Summary and Certification <i>See recommended <u>content</u></i> <i>Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital signature. "N/A" only if submission is not a Class III 510(k).</i> | <input type="checkbox"/> | X | <input type="checkbox"/> | |
| | Comments: | | | | |
| 7. | If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (<u>FDA Form 3654</u>) or includes detailed information about how and the extent to which the standard has been followed <i>There should be a completed form for each referenced national or international standard.</i> <i>"N/A" only if submission does not reference any standards.</i> | X | | <input type="checkbox"/> | |
| | Comments: | | | | |
| 8. | Does submission contain clinical data? <i>Select "N/A" for this item and 8.a. and 8.b. if the submission does not contain clinical data. If submission does contain clinical data, parts a. and b. must be answered "yes" for the 510(k) to be complete.</i> | <input type="checkbox"/> | <input type="checkbox"/> | X | |
| | a. | Submission includes Financial Certification/Disclosure Statement | <input type="checkbox"/> | X | <input type="checkbox"/> |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | | |
|---|---------------------------|---|--------------------------|--------------------------|--------------------------|
| Submission should be designated RTA if not addressed | | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | | |
| | | <ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A | No |
| | b. | Submission includes Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) | <input type="checkbox"/> | X | <input type="checkbox"/> |
| | | Comments: | | | |
| | 9. | If this is a bundled submission, the submission has been appropriately bundled [i.e., the correct user fee(s) have been paid for the devices/indications (section 738 of the FD&C Act)] <u>See Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission.</u> <i>"N/A" if not a bundled submission</i> | | X | <input type="checkbox"/> |
| | | Comments: | | | |
| | 10. | The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions. | <input type="checkbox"/> | | X |
| | a. | If there were prior submissions: within current submission, the sponsor has identified where in the current submission any issues related to substantial equivalence outlined in prior communications are addressed. | <input type="checkbox"/> | | X |
| | | Comments: No statement is made with regards to prior submissions for the same device | | | |
| B. | Device Description | | | | |
| | 11. | If there is a device-specific guidance document or special controls applicable to this submission, documentation has been provided to establish that the submitter has followed the recommendations in the applicable device-specific guidance document or special controls | <input type="checkbox"/> | <input type="checkbox"/> | X |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | |
|---|---|------------|------------|--------------------------|
| Submission should be designated RTA if not addressed | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | |
| | | Yes | N/A | No |
| | <ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | | | |
| | regarding the device description or otherwise met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "No" if the submission does not include a rationale for any omitted information or any alternative approaches.</i> <i>Select "N/A" if there is no device-specific guidance document</i> | | | |
| | Comments: Complete chemical composition (including identification of all color additives) is not provided for the device. | | | |
| | 12. All descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including: | | | |
| | a. A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect. | X | | <input type="checkbox"/> |
| | b. A description of all conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient. | X | | <input type="checkbox"/> |
| | c. A list and description of each model for which clearance is requested. <i>Select "N/A" if there is only one model.</i> | | X | <input type="checkbox"/> |
| | Comments: | | | |
| | 13. Where applicable, submission contains engineering drawing(s), schematics, illustrations and/or figures of the device that are clear and legible, and include dimensions | | X | <input type="checkbox"/> |
| | a. If engineering drawings, schematics, illustrations and/or figures are provided, one is provided for each model to be marketed | | X | <input type="checkbox"/> |
| | Comments: | | | |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | |
|---|---|--------------------------|------------|--------------------------|
| Submission should be designated RTA if not addressed | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | |
| | <ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A | No |
| 14. | If device is intended to be marketed with multiple components, accessories, and/or as part of a system, <i>Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i> | | X | |
| a. | A description (as detailed in item 12.a. and b. and 13 above) is provided for each component or accessory. | | X | <input type="checkbox"/> |
| b. | A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. <i>Select "N/A" if the submission states that the component(s)/ accessory(ies) do not have a prior 510(k) clearance.</i> | <input type="checkbox"/> | X | |
| Comments: | | | | |
| C. | Substantial Equivalence Discussion | | | |
| 15. | Submitter has identified a predicate(s) device | X | | <input type="checkbox"/> |
| a. | Predicate's 510(k) number, trade name, and model number (if applicable) provided | X | | <input type="checkbox"/> |
| b. | The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing | X | | <input type="checkbox"/> |
| Comments: | | | | |
| 16. | Submission includes a comparison of the following for the predicate(s) and subject device | | | |
| a. | Indications for use | X | | <input type="checkbox"/> |
| b. | Technology, including features, materials, and principles of operation | X | | <input type="checkbox"/> |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | |
|---|---|-----|-----|--------------------------|
| Submission should be designated RTA if not addressed | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | |
| | <ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A | No |
| | Comments: | | | |
| 17. | <p>Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act)</p> <p><i>If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that due to potential differences in manufacturing that may not be known to the submitter, no identified differences does not necessarily mean that no performance testing is needed.</i></p> | X | | <input type="checkbox"/> |
| | Comments: | | | |
| D. | Proposed Labeling (see also 21 CFR part 801) | | | |
| 18. | Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual), and advertisements that describe the device, its intended use, and the directions for use | | | |
| | a. Indications for use stated in labeling (21 CFR 801.61) and identical to IFU form and 510(k) Summary (if applicable) | X | | <input type="checkbox"/> |
| | b. Directions for use included (including relevant hazards, warnings, precautions, contraindications), including directions for layperson (see 21 CFR 801.5) unless submission states that device qualifies for exemption per 21 CFR 801 Subpart D. | | | X |
| | Comments: Directions for use are not provided and the exemption in 21 CFR 801 Subpart D is not cited. | | | |

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|---|--|---|-------------------------------------|--------------------------|
| Submission should be designated RTA if not addressed | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | |
| | | <ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A |
| | | | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| | 19. | If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also <u>Alternative to Certain Prescription Device Labeling Requirements</u>] <i>Select "N/A" if not indicated for prescription use.</i> | X | <input type="checkbox"/> |
| | | Comments: | | |
| | 20. | General labeling provisions | | |
| | a. | Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1) | X | <input type="checkbox"/> |
| | b. | Labeling includes device common or usual name (21 CFR 801.61) | X | <input type="checkbox"/> |
| | | Comments: | | |
| | 21. | If there is a device-specific guidance, special controls, or regulation, the provided labeling establishes that the submitter has followed the recommendations in the applicable guidance document, special controls, or regulation, or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no device-specific guidance or regulation.</i> | <input type="checkbox"/> | X |
| | | Comments: | | |
| | 22. | If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. <i>Select "N/A" if not an in vitro diagnostic device.</i> | <input type="checkbox"/> | X |
| E. | Performance Data – General | | | |
| | Submission: <i>(one of the below must be checked)</i> X does <input type="checkbox"/> does not | | | |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | |
|---|---|--------------------------|--------------------------|--------------------------|
| Submission should be designated RTA if not addressed | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | |
| | <ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A | No |
| | contain performance data. <i>If "does not" is selected, the performance data-related criteria below are omitted from the checklist.</i> | | | |
| | Comments: | | | |
| 23. | Full test report is provided for each completed test to explain how the data generated from the test supports a finding of substantial equivalence. (A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, and conclusions.) | <input type="checkbox"/> | X | <input type="checkbox"/> |
| | Comments: | | | |
| 24. | Submission includes document to establish that the submitter has followed the recommendations for performance data outlined in the applicable device-specific guidance document or special controls, or otherwise met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no device-specific guidance document.</i> | <input type="checkbox"/> | X | <input type="checkbox"/> |
| | Comments: | | | |
| 25. | If literature was used as performance data, submission includes reprints or a summary of each article, and a discussion as to how each article is applicable to support the substantial equivalence of the subject device to the predicate. | <input type="checkbox"/> | X | <input type="checkbox"/> |
| | Comments: | | | |
| 26. | If an animal study was conducted, <i>Select "N/A" if no animal study was conducted.</i> | <input type="checkbox"/> | X | <input type="checkbox"/> |
| a. | Submission includes a study protocol and final study report to explain how the data generated from the study supports a finding of substantial equivalence. (A final study report includes a contributing scientist report for each preclinical endpoint of | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) | | | | | |
|---|----------------------|---|--------------------------|--------------------------|--------------------------|
| Submission should be designated RTA if not addressed | | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | | |
| | | <ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A | No |
| | | evaluation within the protocol, such as performance/handling, in life, imaging, pathology, etc.) | | | |
| | b. | Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination. | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | Comments: | | | |
| F. | Sterilization | | | | |
| | | Submission states that the device and/or accessories are: <i>(one of the below must be checked)</i> <input type="checkbox"/> sterile <input type="checkbox"/> non-sterile but sterilized by the end user <input checked="" type="checkbox"/> non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist.</i> <i>If information regarding the sterility status of the device is not provided, select "No."</i> | | | <input type="checkbox"/> |
| | | Comments: | | | |
| | 27. | Assessment of the need for sterilization information | | X | |
| | a. | Identification of device, and/or accessories, and/or components that are provided sterile. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | b. | Identification of device, and/or accessories, and/or components | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | | | | |
|---|-----|--|---|--------------------------|--------------------------|--------------------------|--|
| Submission should be designated RTA if not addressed | | | | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | | | | |
| | | | <ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A | No | |
| | | | that are end user sterilized | | | | |
| | | c. | Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| | | Comments: | | | | | |
| | 28. | If the device, and/or accessory, and/or a component is provided sterile: <i>Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.</i> | | | | X | |
| | | a. | Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.) | <input type="checkbox"/> | | <input type="checkbox"/> | |
| | | b. | A description of method to validate the sterilization cycle (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided | <input type="checkbox"/> | | <input type="checkbox"/> | |
| | | c. | For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. <i>Select "N/A" if not sterilized using chemical sterilants.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| | | d. | Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package) | <input type="checkbox"/> | | <input type="checkbox"/> | |
| | | e. | Sterility Assurance Level (SAL) stated | <input type="checkbox"/> | | <input type="checkbox"/> | |
| | | f. | If device is blood-contacting, a permanent implant, or contacts cerebrospinal fluid, or device is labeled "non-pyrogenic," submission contains a description of the endotoxin method used to | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

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|---|-------------------|---|--------------------------|--------------------------|--------------------------|
| Submission should be designated RTA if not addressed | | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | | |
| | | <ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A | No |
| | | make a determination (e.g., LAL), endotoxin release specification (e.g., 20 EU/device), and a rationale for the specification. <i>Select "N/A" if device is not blood-contacting, not a permanent implant, does not contact cerebrospinal fluid, and is not labeled "non-pyrogenic." Select "N/A" if a rationale for omission is provided.</i> | | | |
| | | Comments: | | | |
| | 29. | All sterility information provided as recommended in the following guidance documents or special controls, or information provided indicating the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach: <i>Either "a" or "b" must be answered "Yes" to be considered complete.</i> | | X | |
| | | a. Device-specific guidance document or special controls <i>Select "N/A" if no device-specific guidance document.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | b. Cross-cutting guidance document (for more information see " <u>Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labeled as Sterile</u> ") <i>Select "N/A" if device-specific guidance followed instead.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Comments: | | | |
| G. | Shelf Life | | | | |
| | 30. | If the device is provided sterile or the device is provided non-sterile and storage conditions (i.e., aging) could impact device safety or effectiveness, address the following: <i>Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.</i> | | X | |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | | |
|---|---|---|--------------------------|-----|--------------------------|
| Submission should be designated RTA if not addressed | | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | | |
| | | <ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A | No |
| | a. | Proposed shelf life/expiry date stated | <input type="checkbox"/> | | <input type="checkbox"/> |
| | b. | Submission includes description of shelf life validation method(s) used to ensure device performance and sterility, as applicable, remain substantially equivalent to that of the predicate device throughout the stated shelf life. | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | Comments: | | | |
| H. | Biocompatibility | | | | |
| | Submission states that there: <i>(one of the below must be checked)</i> X are <input type="checkbox"/> are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."</i> | | | | <input type="checkbox"/> |
| | Comments: | | | | |
| | 31. | Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present | | | X |
| | | Comments: Complete chemical composition (including identification of all color additives) is not provided for the device | | | |
| | 32. | Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) | <input type="checkbox"/> | | X |
| | | Comments: Type of contact classification not stated | | | |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | |
|---|--|--------------------------|-----|--------------------------|
| Submission should be designated RTA if not addressed | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | |
| | | Yes | N/A | No |
| | <ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | | | |
| | 33. Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate). | X | | <input type="checkbox"/> |
| I. | Software | | X | |
| | Submission states that the device: <i>(one of the below must be checked)</i> <input type="checkbox"/> does X does not contain software. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."</i> | | | <input type="checkbox"/> |
| | Comments: | | | |
| | 34. All appropriate categories of software verification and validation documentation provided based on stated level of concern, as described in <u>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</u> , or the submitter has provided documentation that it has otherwise met the applicable statutory or regulatory criteria through an alternative approach. | <input type="checkbox"/> | X | <input type="checkbox"/> |
| | Comments: | | | |

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|---|---|--------------------------|------------|--------------------------|
| Submission should be designated RTA if not addressed | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | |
| | <ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | Yes | N/A | No |
| J. | EMC and Electrical Safety | | X | |
| | Submission states that the device: <i>(one of the below must be checked)</i> <input type="checkbox"/> does <input checked="" type="checkbox"/> does not require EMC and Electrical Safety evaluation. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."</i> | | | <input type="checkbox"/> |
| | Comments: | | | |
| | 35. Submission includes evaluation of electrical safety per IEC 60601-1 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements. | <input type="checkbox"/> | X | <input type="checkbox"/> |
| | Comments: | | | |
| | 36. Submission includes evaluation of electromagnetic compatibility per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable | <input type="checkbox"/> | X | <input type="checkbox"/> |

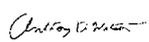
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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | |
|---|---|--------------------------|--------------------------|--------------------------|
| Submission should be designated RTA if not addressed | | | | |
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | |
| | | Yes | N/A | No |
| | <ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. | | | |
| | statutory and regulatory requirements. | | | |
| | Comments: | | | |
| K. | Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12)) | | X | |
| | Submission indicates that device: <i>(one of the below must be checked)</i> <input type="checkbox"/> is <input type="checkbox"/> is not an in vitro diagnostic device (IVD). <i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i> | | | |
| | Comments: | | | |
| | 37. Submission includes the following analytical studies, including associated protocols and line data: | | X | |
| | a. Precision/reproducibility (at least 3 sites generally necessary) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | b. Accuracy (includes linearity, assay cut-off, method comparison or comparison to clinical outcome, matrix comparison, reference range, and stability protocol and acceptance criteria) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | c. Sensitivity (detection limits (LoB, LoD, and LoQ)) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | d. Analytical specificity | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | Comments: | | | |

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Decision: Accept ___ Refuse to Accept X

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

| Digital Signature Concurrence Table | |
|--|---|
| Reviewer Sign-Off | Michael E. Adjodha -S 2012.11.14 08:34:10 -05'00' |
| Branch Chief Sign-Off | Mary S. Runner 2012.11.14 08:50:55 -05'00' |
| Division Sign-Off |  DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402 Date: 2012.11.14 15:47:22 -05'00' |

Jones, Ashlee *

From: Microsoft Outlook
To: 'marilin@tcsdentalinc.com'
Sent: Tuesday, November 06, 2012 10:12 AM
Subject: Relayed: K123396 Ack. Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

'marilin@tcsdentalinc.com' (marilin@tcsdentalinc.com) <mailto:marilin@tcsdentalinc.com>

Subject: K123396 Ack. Letter



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 06, 2012

THERMOPLASTIC COMFORT SYSTEMS, INC.
2619 LIME AVENUE
SIGNAL HILL, CALIFORNIA 90755
ATTN: MARLIN POSCA

510k Number: K123396

Received: 11/5/2012

Product: I.FLEX BY TCS

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

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

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

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Records Processed under FOIA Request 2013-1691; Released by CDRH on 10/27/15
Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

K123390

Thermoplastic Comfort System, Inc.

510(k) for i.flex by TCS Denture Resin

Traditional 510(k) Original Submission

November 2, 2012



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Section 1.0: Medical Device User Fee Cover Sheet (Form FDA 3601)

Exemptions and Waivers

No waivers or exemptions are applied to this device.

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. See Instructions for OMB Statement.

| | | |
|--|---|---|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET | | PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check. |
| A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html | | |
| 1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) THERMOPLASTIC COMFORT SYSTEMS INC 2619 LIME AVENUE SIGNAL HILL CA 907552718 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0343 | 2. CONTACT NAME marilin posca 2.1 E-MAIL ADDRESS marilin@tcsdentalinc.com 2.2 TELEPHONE NUMBER (include Area code) 562-4262970 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 562-4265154 | |
| 3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type: | | |
| <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice | 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) | |
| 4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: | | |
| 5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information) | | |
| 6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially | | |
| 7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO | | |
| PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.] | | |
| 8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4) | | 30-Oct-2012 |

Form FDA 3501 (01/2007)

"Close Window" [Print Cover sheet](#)



Section 2.0: CDRH Premarket Review Submission Cover Sheet

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

| | | |
|--|---|---|
| Date of Submission November 2, 2012 | User Fee Payment ID Number (b)(4) | FDA Submission Document Number (if known) K123396 |
|--|---|---|

SECTION A TYPE OF SUBMISSION

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

| | | | |
|---|--------------------------------|---|---------------|
| Company / Institution Name Thermoplastic Comfort Systems, Inc. | | Establishment Registration Number (if known) 2032807 | |
| Division Name (if applicable) | | Phone Number (including area code) 562-426-2970 | |
| Street Address 2619 Lime Avenue | | FAX Number (including area code) 562-426-5154 | |
| City Signal Hill | State / Province California | ZIP/Postal Code 90755 | Country US |
| Contact Name Marilyn Posca | | | |
| Contact Title President | | Contact E-mail Address marilin@tcsdentalinc.com | |

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

| | | | |
|-------------------------------|------------------|------------------------------------|---------|
| Company / Institution Name | | | |
| Division Name (if applicable) | | Phone Number (including area code) | |
| Street Address | | FAX Number (including area code) | |
| City | State / Province | ZIP Code | Country |
| Contact Name | | | |
| Contact Title | | Contact E-mail Address | |

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR IDE

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

Other Reason (*specify*):

SECTION D2

REASON FOR APPLICATION - IDE

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

Other Reason (*specify*):

SECTION D3

REASON FOR SUBMISSION - 510(k)

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

Other Reason (*specify*):

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

| | | | | | | | | |
|--|-----|---|--|---|--|---|--|---|
| Product codes of devices to which substantial equivalence is claimed | | | | | | | | Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement |
| 1 | EBI | 2 | | 3 | | 4 | | |
| 5 | | 6 | | 7 | | 8 | | |

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

| | 510(k) Number | Trade or Proprietary or Model Name | Manufacturer |
|---|---------------|------------------------------------|---|
| 1 | K063626 | DuraFlex | Cosmetic Dental Materials, Inc. (The Myerson Company, Ltd.) |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
Resin, Denture, Relining, Repairing, Rebasing

| | Trade or Proprietary or Model Name for This Device | Model Number |
|---|--|--------------|
| 1 | i.flex by TCS | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

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

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

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

| | | |
|--------------------------------|--|---|
| Product Code EBI | C.F.R. Section (if applicable) 872.3760 | Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified |
| Classification Panel Dental | | |

Indications (from labeling)
i.flex by TCS is a thermoplastic resin used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

| | | | | | |
|--|--|--|--|---|--|
| <input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | | Facility Establishment Identifier (FEI) Number | | <input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler | |
| Company / Institution Name Thermoplastic Comfort Systems, Inc. | | | Establishment Registration Number 2032807 | | |
| Division Name (if applicable) | | | Phone Number (including area code) 562-426-2970 | | |
| Street Address 2619 Lime Avenue | | | FAX Number (including area code) 562-426-5154 | | |
| City Signal Hill | | State / Province California | ZIP Code 90755 | Country US | |
| Contact Name Marilyn Posca | | Contact Title President | | Contact E-mail Address marilin@tcsdentalinc.com | |

| | | | | | |
|---|--|--|------------------------------------|--|--|
| <input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | | Facility Establishment Identifier (FEI) Number | | <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler | |
| Company / Institution Name | | | Establishment Registration Number | | |
| Division Name (if applicable) | | | Phone Number (including area code) | | |
| Street Address | | | FAX Number (including area code) | | |
| City | | State / Province | ZIP Code | Country | |
| Contact Name | | Contact Title | | Contact E-mail Address | |

| | | | | | |
|---|--|--|------------------------------------|--|--|
| <input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | | Facility Establishment Identifier (FEI) Number | | <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler | |
| Company / Institution Name | | | Establishment Registration Number | | |
| Division Name (if applicable) | | | Phone Number (including area code) | | |
| Street Address | | | FAX Number (including area code) | | |
| City | | State / Province | ZIP Code | Country | |
| Contact Name | | Contact Title | | Contact E-mail Address | |

SECTION I

UTILIZATION OF STANDARDS

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

| | Standards No. | Standards Organization | Standards Title | Version | Date |
|---|---------------------------|------------------------|--|---------|------|
| 1 | 10993-5:2009 | ISO | Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity | | |
| 2 | 10993-10:2010 | ISO | Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization | | |
| 3 | 10993-3:2009 | ISO | Biological Evaluation of Medical Devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity | | |
| 4 | Specification No. 12:2002 | ANSI/ADA | Denture Base Polymers | | |
| 5 | Specification No. 80:2001 | ANSI/ADA | Dental Materials - Determination of Color Stability | | |
| 6 | | | | | |
| 7 | | | | | |

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

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

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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



Section 3.0: 510(k) Cover Letter

K123390



KS4

FDA CDRH DMC

NOV 05 2012

Received

2 November 2012

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center – WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

Attention: Document Mail Clerk

RE: PreMarket Notification for Denture Resin – i.flex by TCS
 Traditional 510(k), Original Submission

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and the Safe Medical Devices Act of 1990 and 21 CFR 807.87, a new notification is being submitted for the i.flex by TCS device that Thermoplastic Comfort Systems, Inc., a US based corporation, proposes to introduce into US interstate commerce for commercial distribution.

Applicant Information

| | |
|------------------|---|
| Applicant's Name | Thermoplastic Comfort Systems, Inc. |
| Address | 2619 Lime Avenue Signal Hill, CA 90755 |
| Telephone | 562-426-2970 |
| Fax Number | 562-426-5154 |
| Contact at TCS | Marilyn Posca President |
| E-mail | marilin@tcsdentalinc.com |

Device Information

| | |
|-------------------------|--|
| Trade name/Product Name | i.flex by TCS |
| Common/Usual Name | Dental resin |
| Classification Name | Resin, Denture, Relining, Repairing, Rebasings |
| Classification Panel | Dental |
| Product Code | EBI |
| Regulation Number | 21 CFR 872.3760 |
| Class | II |

Thermoplastic Comfort Systems wishes to use the following device as the predicate:

| | |
|---------------|--|
| Manufacturer | Cosmetic Dental Materials, Inc. (The Myerson Company, Ltd.) |
| Trade Name | DuraFlex |
| 510(k) Number | K063626 |



The principal factors about the Design and Use of the Device are summarized in the table below.

| Question | YES | NO |
|--|-----|----|
| Is the device intended for prescription use (21 CFR 801 Subpart D)? | YES | |
| Is the device intended for over-the-counter use (21 CFR 807 Subpart C)? | | NO |
| Does the device contain components derived from a tissue or other biologic source? | | NO |
| Is the device provided sterile? | | NO |
| Is the device intended for single use? | | NO |
| Is the device a reprocessed single use device? | | NO |
| If yes, does this device type require reprocessed validation data? | | NO |
| Does the device contain a drug? | | NO |
| Does the device contain a biologic? | | NO |
| Does the device use software? | | NO |
| Does the submission include clinical information? | | NO |
| Is the device implanted? | | NO |

We appreciate your earliest attention to this submission.

Sincerely,

Marilyn Posca
President



Section 4.0: Indications for Use Statement



510(k) Number (if known):

Device Name: i.flex by TCS

Indications For Use:

i.flex by TCS is a thermoplastic resin used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

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)



Section 5.0: 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

| | |
|---------------------|---|
| Manufacturer | Thermoplastic Comfort Systems, Inc. |
| Address | 2619 Lime Avenue Signal Hill, CA 90755 |
| Telephone | 562-426-2970 |
| Fax Number | 562-426-5154 |
| Contact at TCS | Marilin Posca President |
| E-mail | marilin@tcsdentalinc.com |

Device Name and Classification

| | |
|-------------------------|--|
| Trade name/Product Name | i.flex by TCS |
| Common/Usual Name | Dental resin |
| Classification Name | Resin, Denture, Relining, Repairing, Rebasings |
| Classification Panel | Dental |
| Product Code | EBI |
| Regulation Number | 21 CFR 872.3760 |
| Class | II |

Predicate Device

| | |
|---------------|--|
| Manufacturer | Cosmetic Dental Materials, Inc. (The Myerson Company, Ltd.) |
| Device Name | DuraFlex |
| 510(k) Number | K063626 |

Device Description

i.flex by TCS is an injection moldable, flexible, thermoplastic resin provided with trace amounts of colorant added to produce shades of pink. The dental resin is packaged in individual use cartridges or in bulk.

i.flex by TCS is used for fabricating removable dental prosthetic appliances such as full and partial dentures, occlusal splints and night guards.



Indications for Use

i.flex by TCS is a thermoplastic resin used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

Substantial Equivalence

The i.flex by TCS device is substantially equivalent to the DuraFlex dental resin (K063626).

The claim of substantial equivalence for the i.flex by TCS is based on intended use, technology and performance specifications. Both the i.flex by TCS and the predicate device are composed of a thermoplastic, ethylene propylene copolymer identified by its CAS registration number 9010-79-1. Both devices are supplied in a natural or clear state as well as in shades of pink. Both materials are supplied in cartridges which are heated to allow for the injection molding of the resin for the fabrication of dental prostheses.

Biocompatibility

Biocompatibility testing of the i.flex by TCS material was conducted in accordance with ISO standards to demonstrate the safety of the device.

The following biocompatibility tests were conducted:

1. Cytotoxicity: Agar overlay per ISO 10993-5:2009
2. Cytotoxicity: MEM elution per ISO 10993-5:2009
3. Delayed-type hypersensitivity (sensitization): Magnusson-Klingman Method per ISO 10993-10:2010
4. Irritation: Intracutaneous Toxicity (ISO) per ISO 10993-10:2010
5. Genotoxicity: Ames Test per ISO 10993-3:2009

The test results confirm that the i.flex by TCS device is non-cytotoxic, non-sensitizing, non-irritating and non-mutagenic.

Performance Testing to Recognized Standards

The i.flex by TCS device was tested to the applicable clauses of the recognized consensus standards for dental materials listed below.

1. ANSI/ADA Specification No. 12:2002/ISO 1567:1999 - Denture Base Polymers
2. ANSI/ADA Specification No. 80:2001/ISO 7491:2000 - Dental Materials – Determination of Color Stability

The study results demonstrate that the i.flex by TCS meets the performance criteria specified in the recognized standards cited or for the performance of the predicate device, DuraFlex, confirming the substantial equivalence of the i.flex by TCS to the predicate device.



Summary of Performance Testing – Conclusion

The results of all testing demonstrate that the i.flex by TCS device does not raise any new significant issues of safety, effectiveness or performance of the device when compared to the existing predicate device.



Section 6.0: Truthful and Accuracy Statement



PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT
[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as the President of Thermoplastic Comfort Systems, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

A handwritten signature in black ink, appearing to read "M. Posca", is written over a horizontal line.

Marilyn Posca
President, Thermoplastic Comfort Systems, Inc.

A handwritten date "10-30-12" is written in black ink over a horizontal line.

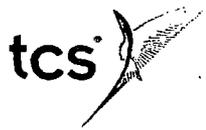
Date

*(Premarket Notification [510(k)] Number)



Section 7.0: Class III Summary and Classification

The i.flex by TCS is a Class II device, thus this section does not apply.



Section 8.0: Financial Certification or Disclosure Statement

No clinical studies are included in this 510(k), thus a Financial Certificate or Disclosure Statement is not required.



Section 9.0: Declarations of Conformity and Summary Report

This is a Traditional 510(k) submission and no Declaration of Conformity is declared. Attached are the Standards Data Reports for 510(k)s for testing completed.

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ANSI/ADA Specification No. 12:2002 - Denture Base Polymers

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #4-117

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ANSI/ADA Specification No. 12:2002 - Denture Base polymers

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|--|--|
| 8.5.3.5.1 | Flexural strength and flexural modulus procedure | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|------------------------------------|--|
| 5.2.9 | Bonding to Synthetic Polymer Teeth | <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *
Not applicable to this device. Test was not conducted.

DESCRIPTION
This is a test requirement for denture base polymers intended for use with synthetic polymer teeth to evaluate the bonding of the resin to the synthetic teeth.

JUSTIFICATION
Device is not used to bond synthetic polymer teeth. Synthetic teeth are held in place mechanically. The device is made of the same material as the predicate device and would have the same bonding characteristics as the predicate device.

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|--------------------------------------|--|
| 5.2.10 | Residual methyl methacrylate monomer | <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *
Not applicable to this device. Test was not conducted.

DESCRIPTION
This is a test for determining the residual methyl methacrylate monomer levels in the device.

JUSTIFICATION
Device is composed of ethylene propylene copolymer and does not contain methyl methacrylate monomer.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ANSI/ADA Specification No. 80:2001 - Dental Materials - Determination of Color Stability

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #4-91

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ANSI/ADA Specification No. 80:2001 - Dental Materials - Determination of Color Stability

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|--|---------------|---|
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| | | |

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-3:2009 - Biological Evaluation of Medical Devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxic

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-117

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-3:2009 - Biological Evaluation of Medical Devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxic

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|--|
|----------------|---------------|--|

TYPE OF DEVIATION OR OPTION SELECTED *
Tests for genotoxicity by the Ames Test was conducted.

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-5:2009 - Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-153

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance:

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² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-5:2009 - Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|--|
| | | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *
Tests for cytotoxicity by agar overlay and MEM elution methods were conducted.

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---------------|---|
| | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-10:2010 - Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-152

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-10:2010 - Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED *
Tests for 1) delayed-type hypersensitivity (sensitization): Magnusson-Klingman Method and 2) irritation: intracutaneous toxicity were performed.

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|---------------|---|
|----------------|---------------|---|

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Section 10.0: Executive Summary

Device Name

| | |
|-------------------------|---|
| Trade name/Product Name | i.flex by TCS |
| Common/Usual Name | Dental resin |
| Classification Name | Resin, Denture, Relining, Repairing, Rebasing |
| Classification Panel | Dental |
| Product Code | EBI |
| Regulation Number | 21 CFR 872.3760 |
| Class | II |

Manufacturer Name and Address

| | |
|----------------|---|
| Manufacturer | Thermoplastic Comfort Systems, Inc. |
| Address | 2619 Lime Avenue Signal Hill, CA 90755 |
| Telephone | 562-426-2970 |
| Fax Number | 562-426-5154 |
| Contact at TCS | Marilyn Posca President |
| E-mail | marilin@tcsdentalinc.com |

Device Description

i.flex by TCS is an injection moldable, flexible, thermoplastic polypropylene random copolymer with trace amounts of colorant added. The polypropylene is purchased in bulk by TCS as a natural colored resin, mixed with colorant at the TCS facility and packaged in individual use cartridges or in bulk.

i.flex by TCS is used for fabricating removable dental prosthetic appliances such as full and partial dentures, occlusal splints and night guards by dental professionals and trained dental technicians. Because it can be used to create completely non-metallic prosthetics, it is suitable for making removable dental prosthetic appliances for metal-allergic patients.

The i.flex by TCS material is an ethylene propylene copolymer with trace amounts of a red pigment added to produce shades of pink. i.flex by TCS is offered in natural (without pigment) and in four different shades of pink (light pink, standard pink, light/dark pink, and dark pink).

Indications for Use

i.flex by TCS is a thermoplastic resin used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.



Substantial Equivalence

The i.flex by TCS is substantially equivalent to the DuraFlex dental resin (K063626).

The claim of substantial equivalence for the i.flex by TCS is based on intended use, technology and performance specifications. Both the i.flex by TCS and the predicate device are composed of a thermoplastic resin. (b)(4) identified by its (b)(4)

(b)(4) Both devices are supplied in a natural or clear state as well as in shades of pink. Both materials are supplied in cartridges which are heated to allow for the injection molding of the dental prostheses. Table 10-1 present the comparison of the i.flex by TCS device to the DuraFlex predicate to support the substantial equivalence to the predicate.

Table 10-1. Substantial Equivalence Comparison Table – i.flex by TCS and DuraFlex

| Characteristics | i.flex by TCS | DuraFlex |
|------------------------|---|---|
| Intended use | i.flex by TCS is a thermoplastic resin used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards. | The DuraFlex material is a thermoplastic resin intended for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards. |
| Product Code | EBI | EBI |
| Regulation No. | 21 CFR 872.3760 | 21 CFR 872.3760 |
| Classification | Class II | Class II |
| Prescription / OTC use | Prescription Use | Prescription Use |
| Description | <p>i.flex by TCS is an injection moldable, flexible, thermoplastic resin provided with trace amounts of colorant added to produce shades of pink. The dental resin is packaged in individual use cartridges or in bulk.</p> <p>i.flex by TCS is used for fabricating removable dental prosthetic appliances such as full and partial dentures, occlusal splints and night guards. Because it can be used to create completely non-metallic prosthetics, it is suitable for making removable dental prosthetic appliances for metal-</p> | The DuraFlex material is a thermoplastic resin that is used to fabricate dental prostheses. The resin is used in an injection molding or pressing device to fabricate prostheses. |



| Characteristics | i.flex by TCS | DuraFlex |
|------------------------|--|--|
| | allergic patients. | |
| Available Shades | Light Pink, Standard Pink, Light-Dark Pink, Dark Pink, Natural | Pink, Medium pink, Dark pink, Clear |
| Use environment | Dental Lab | Dental Lab |
| Material | (b)(4) | |
| Method of use | Injection Molding Process | Injection Molding Process |
| Principal of operation | The i.flex by TCS is supplied in cartridges. The cartridges are heated to 288°C for 11 minutes and the molten resin is injected into the mold to form the dental prosthesis. | The DuraFlex material is supplied in cartridges. The cartridges are heated to 230°C for 12.5 minutes and the molten resin is injected into the mold to form the dental prosthesis. |

Performance Characteristics – Biocompatibility

Performance data to demonstrate compliance to Recognized Consensus Standards for biocompatibility was obtained. Test data is summarized in Section 15.0 Biocompatibility. Test reports can be found in Attachments 15-1 to 15-5. The product was tested and is in compliance with the following standards:

| No. | Recognized Consensus Standard | Application |
|-----|-------------------------------|--|
| 1 | ISO 10993-5:2009 | Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity |
| 2 | ISO 10993-10:2010 | Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization |
| 3 | ISO 10993-3:2009 | Biological Evaluation of Medical Devices Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity |

The test results confirm that the i.flex by TCS device is non-cytotoxic, non-sensitizing, non-irritating and non-mutagenic. The i.flex by TCS device therefore meets the biocompatibility safety requirements for use as a denture base polymer.



Performance Characteristics – Standards for Dental Resins

Performance data to demonstrate compliance to Recognized Consensus Standards was obtained. The test data is summarized in Section 18.0 Performance Testing – Bench. The product was tested in compliance with the following standards:

| No. | Recognized Consensus Standards | Application |
|-----|--|---|
| 1 | ANSI/ADA Specification No. 12:2002/ISO 1567:1999 | Denture Base Polymers |
| 2 | ANSI/ADA Specification No. 80-2001/ISO 7491:2000 | Dental Materials – Determination of Color Stability |

The study results presented demonstrate that the i.flex by TCS meets the performance criteria specified in the recognized standards cited. In the instance where the device failed to meet the specifications for ultimate flexural strength and flexural modulus, testing of the predicate device, DuraFlex, gave similar results confirming the substantial equivalence of the i.flex by TCS to the predicate device.

Conclusion

The results of the performance testing for the i.flex by TCS device in accordance with the recognized consensus standards demonstrates that the i.flex by TCS device does not raise any new significant issues of performance of the device when compared to the existing predicate device.



Section 11.0: Device Description

11.1 General System Description

i.flex by TCS is an injection moldable, flexible, thermoplastic (b)(4) random (b)(4) with (b)(4). The (b)(4) random (b)(4) is purchased in bulk by TCS as a natural resin (b)(4) at the TCS facility and packaged in individual use cartridges or in bulk.

i.flex by TCS is used for fabricating removable dental prosthetic appliances such as full and partial dentures, occlusal splints and night guards. Because it can be used to create completely non-metallic prosthetics, it is suitable for making removable dental prosthetic appliances for metal-allergic patients.

The i.flex by TCS material is a (b)(4) of a (b)(4). i.flex by TCS is offered in natural (without pigment) and in four different shades of pink.



Section 12.0: Substantial Equivalence Discussion

12.1 Substantial Equivalence Comparison

The i.flex by TCS is substantially equivalent to the DuraFlex dental resin (K063626).

The claim of substantial equivalence for the i.flex by TCS is based on intended use, technology and performance specifications. Both the i.flex by TCS and the predicate device are composed of a thermoplastic, (b)(4) identified by its (b)(4). Both devices are supplied in a natural or clear state as well as in shades of pink. The materials are supplied in cartridges which are heated to allow for the injection molding of the resin for the fabrication of dental prostheses.

The ultimate flexural strength and flexural modulus were determined for both devices using the same test method. Both devices demonstrated similar physical properties for ultimate flexural strength and flexural modulus to support the substantial equivalence of the devices.

Table 10-1 presents the comparison of the i.flex by TCS device to the predicate DuraFlex device to support the substantial equivalence to the predicate.

Table 10-1. Substantial Equivalence Comparison Table – i.flex by TCS and DuraFlex

| Characteristics | i.flex by TCS | DuraFlex |
|------------------------|---|---|
| Intended use | i.flex by TCS is a thermoplastic resin used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards. | The DuraFlex material is a thermoplastic resin intended for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards. |
| Product Code | EBI | EBI |
| Regulation No. | 21 CFR 872.3760 | 21 CFR 872.3760 |
| Classification | Class II | Class II |
| Prescription / OTC use | Prescription Use | Prescription Use |
| Description | i.flex by TCS is an injection moldable, flexible, thermoplastic resin provided with trace amounts of colorant added to produce shades of pink. The dental resin is packaged in individual use | The DuraFlex material is a thermoplastic resin that is used to fabricate dental prostheses. The resin is used in an injection molding or pressing device to fabricate prostheses. |



| Characteristics | i.flex by TCS | DuraFlex |
|---|---|---|
| | cartridges or in bulk. i.flex by TCS is used for fabricating removable dental prosthetic appliances such as full and partial dentures, occlusal splints and night guards. | |
| Available Shades | Light Pink, Standard Pink, Light-Dark Pink, Dark Pink, Natural | Pink, Medium pink, Dark pink, Clear |
| Use environment | Dental Lab | Dental Lab |
| Material | (b)(4) | |
| Method of use | Injection Molding Process | Injection Molding Process |
| Principal of operation | The i.flex by TCS is supplied in cartridges. The cartridges are heated to 288°C for 11 minutes and the molten resin is injected into the mold to form the dental prosthesis. | The DuraFlex is supplied in cartridges. The cartridges are heated to 230°C for 12.5 minutes and the molten resin is injected into the mold to form the dental prosthesis. |
| Biocompatibility | The i.flex by TCS material is non-cytotoxic, non-sensitizing, non-irritating and non-mutagenic per ISO 10993 test methods. | Not Available |
| Ultimate flexural strength | 1220 ± 27 MPa | 1076 ± 102 MPa |
| Flexural modulus | 27 ± 2 MPa | 25 ± 1 MPa |
| Color Stability per ANSI/ADA Specification No. 80/ISO 7491:2000 | The i.flex by TCS samples tested demonstrated no color change or visual distortions after light exposure under the conditions specified in the referenced standards to confirm the color stability of the material. | Not Available |

12.2 Conclusion

The i.flex by TCS device is substantially equivalent to the DuraFlex device based upon intended use, technology and performance specifications.



Section 13.0: Proposed Labeling

13.1 Indications for Use

The following Indication for Use statement is proposed for the device:

i.flex by TCS is a thermoplastic resin used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

13.2 Instructions for Use – Package Label/Insert

The i.flex by TCS is packaged with a package insert that provides device label information as well as instructions for use.

A copy of the i.flex by TCS package insert can be found in Attachment 13-1.

13.3 Description of Packaging

The i.flex by TCS is supplied packaged in aluminum cartridges which allows the user to heat the material for injection molding in the dental prosthesis fabrication process. The cartridge sizes and approximate material weight is listed in Table 13-1.

Table 13-1. i.flex by TCS Cartridge Sizes

| Cartridge Size/Diameter | Approximate weight (oz.) |
|-------------------------|--------------------------|
| Small 25 mm | ~ 0.28 oz. |
| Medium 25 mm | ~ 0.63 oz. |
| Large 25 mm | ~ 0.90 oz. |
| Medium 28 mm | ~ 0.69 oz. |
| Large 28 mm | ~ 0.92 oz. |
| Medium 22 mm | ~ 0.63 oz. |
| Large 22 mm | ~ 0.78 oz. |

The material is also provided in bulk packages.

13.4 Attachments

Attachment 13-1 – i.flex by TCS Package Label/Insert



Section 14.0: Sterilization and Shelf-Life

The i.flex by TCS device is not sterilized and does not have a specified shelf-life.



Section 15.0: Biocompatibility

15.1 Biocompatibility Testing – Sample Preparation and Study Protocol

Biocompatibility testing of the i.flex by TCS device was conducted in accordance with ISO standards to demonstrate the safety of the device.

Test samples were manufactured in accordance with documented manufacturing procedures and each lot was documented in a device history record. The samples used in the testing were i.flex by TCS Dark Pink, Shade 4, Lot 35061512. The Dark Pink, Shade 4 color was selected because it has the highest concentration of colorant for the i.flex by TCS color shades offered.

The following biocompatibility tests were conducted:

- a. Cytotoxicity: Agar overlay per ISO 10993-5:2009
- b. Cytotoxicity: MEM elution per ISO 10993-5:2009
- c. Delayed-type hypersensitivity (sensitization): Magnusson-Klingman Method per ISO 10993-10:2010
- d. Irritation: Intracutaneous Toxicity (ISO) per ISO 10993-10:2010
- e. Genotoxicity: Ames Test per ISO 10993-3:2009

Test samples were sent to Nelson Laboratories, Salt Lake City, UT for the conduct of the studies.

15.2 Biocompatibility Test Results

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15.3 Conclusions

The test results confirm that the i.flex by TCS device is non-cytotoxic, non-sensitizing, non-irritating and non-mutagenic. The i.flex by TCS device therefore meets the biocompatibility safety requirements for use as a denture base polymer.



15.4 Attachments

Attachment 15-1, Agar Overlay GLP Report

Attachment 15-2, MEM Elution GLP Report

Attachment 15-3, ISO 10993 Part 10 Guinea Pig Maximization Sensitization Test Report

Attachment 15-4, ISO/USP Intracutaneous Reactivity Test in Rabbits Test Report

Attachment 15-5, Ames Test (Reverse Mutation Assay) Report



Section 16.0: Software

The i.flex by TCS device does not contain any software.



Section 17.0: Electromagnetic Compatibility and Electrical Safety

The i.flex by TCS device is not an electrical device and as such, does not have any requirements for electromagnetic compatibility and electrical safety testing.



Section 18.0: Performance Testing – Bench

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(b) (4)

(b) (4)

(b) (4)



Section 19.0: Performance Testing – Animal

No animal testing was conducted for the i.flex by TCS device, thus this section does not apply.



Section 20.0: Performance Testing - Clinical

No clinical testing was conducted for the i.flex by TCS device, thus this section does not apply.



Section 21.0: Attachments

- Attachment 13-1 i.flex by TCS Package Insert**
- Attachment 15-1 Agar Overlay GLP Report**
- Attachment 15-2 MEM Elution GLP Report**
- Attachment 15-3 ISO 10993 Part 10 Guinea Pig Maximization Sensitization Test Report**
- Attachment 15-4 ISO/USP Intracutaneous Reactivity Test in Rabbits Test Report**
- Attachment 15-5 Ames Test (Reverse Mutation Assay) Report**



Attachment 13-1
i.flex by TCS Package Insert



www.tcsdentalinc.com

i.flex by tcs®
Thermoplastic Dental Resin
 For the Manufacturer of Removable Dental Prosthetics

LOT _____

SIZE

- Small Nt. Wt: ~0.28 oz. (~7.9g) each tube
- Medium Nt. Wt: ~0.63 oz. (~17.5g) each tube
- Large Nt. Wt: ~0.90 oz. (~25.5g) each tube

SHADE

- tcs® 1 Light Pink
- tcs® 2 Standard Pink
- tcs® 3 Light/Dark Pink
- tcs® 4 Dark Pink
- tcs® Natural
- Other _____

-For Professional Use-

MADE IN THE USA
 L031411 Rev NEW



MOSS GmbH
 Schiffgraben 41
 30175 Hannover, Germany



Thermoplastic Dental Resin: *For the Manufacture of Removable Dental Prosthetics*

Indicated Use: Removable Partial Dentures
Not Suitable For: Fixed Restorations, Unilaterals, Complete Dentures
Warnings: For Professional Use Only
 Use eye protection and heat-resistant gloves during injection process
 Use proper ventilation, vacuum system and mask during finishing stage.

- Instructions:**
- Once removed from sealed plastic bag, store cartridges in a dry place and at 90°F to 100°F (32°C to 38°C) at all times or at least 12 hours prior to use.
 - Melt i.flex according to manufacturer's instructions for type of furnace being utilized. Approximately 550°F (288°C) for 11 minutes.
 - Proceed using standard methods and practices for thermoplastics. (See TCS Injection System Operators Manual for detailed instructions)

FOR PROFESSIONAL USE ONLY

Available Shades:
 Light, Standard, Light-Dark, Dark, Natural

Available Sizes:
 Small, Medium, Large



Thermoplastic Comfort Systems, Inc.
 2619 Lime Ave. Signal Hill, CA 90755 U.S.A
www.tcsdentalinc.com / www.facebook.com/tcsdental



Attachment 15-1
Agar Overlay GLP Report

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 07/27/15



Attachment 15-2
MEM Elution GLP Report

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2013-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15



Attachment 15-3

ISO 10993 Part 10 Guinea Pig Maximization Sensitization Test Report

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2013-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-069; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 6/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2013-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-069; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-069; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 6/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2018-069; Released by CDRH on 07/27/15



Attachment 15-4
ISO/USP Intracutaneous Reactivity Test in Rabbits Test Report

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-069; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2013-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2013-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2013-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-069; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2018-069; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2013-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2013-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15

REFERENCES

| | |
|--------------------|---|
| SRC SOP | Sinclair Research Center, LLC, Standard Operating Procedure Manual |
| ISO 10993-10:2010 | Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization |
| ISO 10993-12:2007 | Biological Evaluation of Medical Devices Part 12: Sample Preparation and Reference Materials |
| FDA 21 CFR-Part 58 | Good Laboratory Practice For Nonclinical Laboratory Studies |
| USDA Policy 12 | Consideration of Alternatives to Painful/Distressful Procedures |



Attachment 15-5
Ames Test (Reverse Mutation Assay) Report

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-069; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 07/27/15

(b)(4) 3rd Party Testing

Records Processed under FOIA Request 2015-169; Released by CDRH on 10/27/15