

K063626

FEB 8 2007



CDM Inc.
812 Water Ave NE
Albany OR 97321
Phone: 541-928-4444
Fax: 541-928-2444

510 (K) Summary

Submitter Name:	CDM Inc.
Submitter Address:	812 Water St NE Albany OR 97321
Submitter Telephone:	541-928-4444
Submitter Facsimile:	541-928-2444
Contact Person:	Bob Bowers Chief Operating Officer
Date Summary Prepared:	October 23, 2006

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

SECTION 9: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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.

9.1 SUBMITTER INFORMATION

- a. Company Name: CDM Inc.
- b. Company Address: 812 Water St NE
Albany OR 97321
- c. Company Telephone: 541-928-4444
Company Facsimile: 541-928-2444
- d. Contact Person: Bob Bowers
Chief Operating Officer
- e. Date Summary Prepared: October 23, 2006

9.2 DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: DuraFlex
- b. Classification Name: Denture relining, repairing or rebasing resin.
21 CFR 872.3760

9.3 IDENTIFICATION OF PREDICATE DEVICES

The DuraFlex material is a thermoplastic resin used to fabricate partial or full removable dentures, as well as occlusal splints and night guards. This material is substantially equivalent to Lucitone FRS Flexible Dental Resin manufactured by Dentsply International. This material is commercially available in the United States.

9.4 DEVICE DESCRIPTION

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 the prostheses.

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

9.5 SUBSTANTIAL EQUIVALENCE

The DuraFlex thermoplastic resin is substantial equivalent to Lucitone FRS Flexible Dental Resin. The fundamental characteristics are similar: the DuraFlex thermoplastic resin is similar in design, function, physical properties and intended use to the predicate device.

9.6 INDICATIONS FOR USE

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.

9.7 TECHNOLOGICAL CHARACTERISTICS

Both the DuraFlex and the predicate device are similar in design, material characteristics, physical properties, handling characteristics, intended use and functionality.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert Bowers
Chief Operating Officer
CDM, Incorporated
812 Water Avenue, NE
Albany, Oregon 97321

FEB 11 2007

Re: K063626

Trade/Device Name: DuraFlex™

Regulation Number: 21 CFR 872.3760

Regulation Name: Denture Relining, Repairing, or Rebasing Resin

Regulatory Class: II

Product Code: EBI

Dated: January 29, 2007

Received: February 05, 2007

Dear Mr. Bowers:

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

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

Page 2 -- Mr. Robert Bowers

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



fs

Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number K063626

Page 1 of 1

Device Name DuraFlex

Indications for use:

The DuraFlex thermoplastic resin is used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.
Dental Device Class II, 872.3760

Do not write below this line - Continue on another page if needed

Prescription Use
(Per 21 CFR 801.109)

OR

Over the counter

(Optional Format 1-2-96)

Suzanne P. [Signature]
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K063626



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert Bowers
Chief Operating Officer
CDM, Incorporated
812 Water Avenue, NE
Albany, Oregon 97321

FEB 8 2007

Re: K063626

Trade/Device Name: DuraFlex™
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: January 29, 2007
Received: February 05, 2007

Dear Mr. Bowers:

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Page 2 – Mr. Robert Bowers

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

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Sincerely yours,



fs

Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number K063626

Device Name DuraFlex

Indications for use:

The DuraFlex thermoplastic resin is used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.
Dental Device Class II, 872.3760

Do not write below this line - Continue on another page if needed

Prescription Use
(Per 21 CFR 801.109)

OR

Over the counter

(Optional Format 1-2-96)



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

510(k) Number: K063626

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

January 24, 2007

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

COSMETIC DENTAL MATERIALS INC
812 WATER ST. N.E.
ALBANY, OR 97321
ATTN: ROBERT BOWERS

510(k) Number: K063626
Product: DURAFLEX

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

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

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

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

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

December 06, 2006

COSMETIC DENTAL MATERIALS INC
812 WATER ST. N.E.
ALBANY, OR 97321
ATTN: ROBERT BOWERS

510(k) Number: K063626
Received: 06-DEC-2006
Product: DURAFLEX

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

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

Please note the following documents as they relate to 510(k) review:
1) Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html.
2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).
3) Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

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

Sincerely yours,

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

K063626

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

510(K) PREMARKET SUBMISSION COVER LETTER

October 23, 2006

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

Dear Sir:

Enclosed is a 510(K) Notification for a new device. Cosmetic Dental Materials Inc (hereafter CDM Inc) establishment registration number is 3034600. The payment identification number for this 510(K) is MD6028638-956733. As instructed by Dr. Susan Runner, because this is a straightforward 510(K) application for a material, chemical analysis (ROHS Screening) would establish our materials substantial equivalence and we could rely on biocompatibility tests filed on predicate materials. I believe this application is correct and complete and I look forward to hearing from you. I will be the contact person for the manufacturer, my contact information is:

Robert Bowers c/o
CDM Inc.
812 Water Ave NE
Albany, OR 97321

Tel: (541) 928-4444
Fax: (541) 928-2444

Thank you,

Robert Bowers,
Chief Operations Officer
CDM Inc.

K28

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CDM Inc. DuraFlex
Original Premarket 510(K) Notification

COVER SHEET

Form Approved OMB No. 0910-511 Expiration Date: August 31, 2005 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. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <http://www.fda.gov/cdrh/mdufma/faqs.html#3a>. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS
(include name, street address, city state, country, and post office code)

COSMETIC DENTAL MATERIALS INC
812 Water St NE
Albany OR 97321
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
931308903

2. CONTACT NAME

Bob Bowers

2.1 E-MAIL ADDRESS

bbowers@cdmonline.biz

2.2 TELEPHONE NUMBER (include Area code)

541-928-4444 303

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

null-null

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

Select an application type:

3.1 Select one of the types below

K2 8

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Premarket notification(510(k)); except for third party

Original Application

- Biologics License Application (BLA)
- Premarket Approval Application (PMA)
- Modular PMA
- Product Development Protocol (PDP)
- Premarket Report (PMR)

Supplement Types:

- Efficacy (BLA)
- Panel Track (PMA, PMR, PDP)
- Real-Time (PMA, PMR, PDP)
- 180-day (PMA, PMR, PDP)

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

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

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

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

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

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

YES NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)

(b)(4)

17-Nov-2006

Form FDA 3601 (08/2003)

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

(b) (4)

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

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7.3 Instructions for Use

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9.1 Submitter Information

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9.4 Device Description

9.5 Substantial Equivalence

9.6 Indications for Use

9.7 Technological Characteristics

Section 10. 510(K) Device Composition

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11.1 Device MSDS Form

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

SECTION 1. 510(K) TRUTHFUL AND ACCURATE STATEMENT

This 510(k) truthful and accurate statement is being submitted in accordance with the requirements by 21 CFR 807.87 (k).

1.1 TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as Chief Operating Officer of CDM Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and that no material fact has been omitted.



(Signature)

Robert J. Bowers

(Typed Name)

12/4/06

(Dated)

*(Premarket Notification[510(K)] Number

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

SECTION 2. DEVICE NAME

The device name, proprietary, common or trade names, and device classification name are being submitted in accordance with the requirements of 21 CFR 807.87 (a).

2.1 PROPRIETARY DEVICE NAME

The proprietary device name for this device is "DuraFlex".

2.2 COMMON OR TRADE NAME

The common or trade name for this device is (b)(4) resin".

2.3 DEVICE CLASSIFICATION NAME

The device classification name for this device as designated by 21 CFR 807.87 (a) is a dental device Class II, 872.3760 denture relining, repairing, or rebasing resin.

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

SECTION 3. 510(K) ESTABLISHMENT REGISTRATION NUMBER

The establishment registration number for this device is being submitted in accordance with 21 CFR 807.87 (b).

3.1 ESTABLISHMENT REGISTRATION NUMBER.

The establishment registration number is 3034600 submitted for this application in accordance with the requirements of 21CFR 807.87 (b).

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

SECTION 4. 510(K) DEVICE CLASSIFICATION

The device classification for this device is being submitted in accordance with the requirements of 21 CFR 807.87 (c).

4.1 DEVICE CLASSIFICATION

The device classification for this device is a Dental Device Class II, 872.3760 denture relining, repairing, or rebasing resin in the 21 CFR Parts 862-892.

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

SECTION 5. 510(K) PROPOSED LABELING

The proposed labeling, sample label and instructions for use for this device are being submitted in accordance with the requirements of 21CFR 807.87 (e).

5.1 PROPOSED LABELING

The proposed labeling for the device will contain the proprietary name of the device "DuraFlex". It will also contain the name and address of the registered establishment, CDM Inc. 812 Water Ave NE Albany OR 97322. Further the label will contain a short phrase of the indications for use, "For fabrication of partial or full removable dentures as well as occlusal splints and night guards."

5.2 PACKAGE LABEL SAMPLE

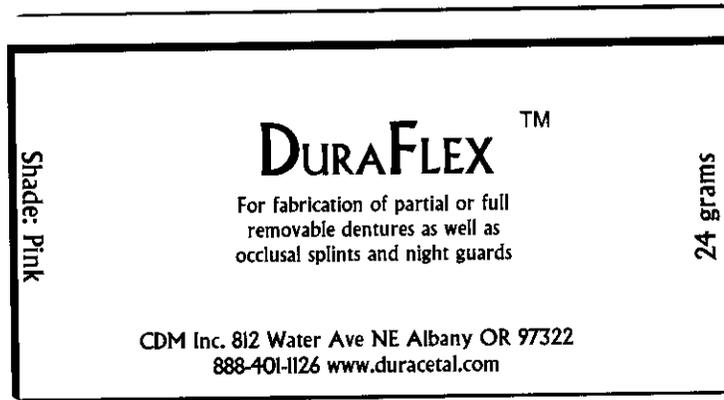
See Fig 5.2.

5.3 INSTRUCTIONS FOR USE

The instruction for use information sheet is attached as figure 5-3 on page 5-3 and 5-4.

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

5.2 PACKAGE LABEL SAMPLE (Fig 5-2)



5-2

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

5.3 INSTRUCTIONS FOR USE (Fig 5-3)

DuraFlex

Material Name: DuraFlex	Manufactured by: Cosmetic Dental Materials	
	812 Water St. NE	
	Albany, OR 97321	
Material Use: denture relining, repairing, or rebasing resin.		
Date: October 25, 2006	Emergency Contact: 888-401-1126	Prepared by: Jesse Droesch

DuraFlex Injection Instructions with the DuraFlex Injection Machine

General information

Injection Temperature	230 C
Processing time (heating time)	15 minutes
Injection time	35 seconds

Precautions

1. Unplug the machine from both electrical and compressed air lines prior to making any adjustments or repairs.
2. Caution must be used to avoid skin contact with heated components. Use heat-resistant gloves when handling warm flasks, cartridges, etc.
3. Proper ventilation, masks, and vacuum systems should be used when grinding and finishing thermoplastics.

Specific Instructions

1. Prepare the flask using typical dental appliance casting and investing techniques.
2. Insert the prepared flask into the closing unit on the top of the machine. Makes sure the flask is secure and the unit is closed well.

3. Preheat the flask and material cartridge prior to injection. The cartridge should be heated at 90C for 30-45 minutes prior to injection.
4. Turn the machine on and program the heating time and temperature for injection.
 - a. Press the "program" button until the green "SP1" is blinking. Use the arrows to adjust the temperature to 230C
 - b. Press the "program" button again until "s.p.t." appears in the display. Use the arrows to adjust the heating time to 15 minutes.
 - c. Press the "program" program button again.
5. Press the "star" button to begin the cycle. "A11" will appear in the display.
6. Once the programmed temperature is reached, "A12" will appear in the display and the timer will start. Insert the DuraFlex cartridge into the machine at this point.
7. After the programmed heating time has elapsed, the piston will engage and hold for 35 seconds. The piston will then disengage. A buzzer will sound and the cycle is complete.
8. Remove the flask from the closing unit and deflask the appliance.
9. Finish the appliance using normal finishing techniques.

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

SECTION 6. 510(K) SUBSTANTIAL EQUIVALENCE COMPARISON

The substantial equivalence comparison for this device is being submitted in accordance with 21CFR 807.87 (f).

6.1 SUBSTANTIAL EQUIVALENCE COMPARISON

The DuraFlex material is a thermoplastic resin used to fabricate partial or full removable dentures, as well as occlusal splints and night guards. This material is substantially equivalent to Lucitone FRS Flexible Dental Resin manufactured by Dentsply International. This material is commercially available in the United States.

6.2 SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

		Success FRS	DuraFlex
1. Indications for use:	Fabrication of partial or full removable dentures including occlusal splints and night guards.	(X)	(X)
2. Materials:	(b)(4) resin.	(X)	(X)
3. Anatomical Sites:	Mouth.	(X)	(X)
4. Creation method:	Dental laboratory pressure injection.	(X)	(X)
5. Passed ROHS:	Contains no hazardous substances. See Table 1.	(X)	(X)

Table 1. Weight percent of elements detected in the dental resin samples via XRF.

Client ID	PSI ID	Approximate Weight Percent				
		Cadmium	Lead	Mercury	Strontium	Barium
DuraFlex	2006-593-01	ND	ND	ND	ND	ND
Valplast	2006-593-02	ND	ND	ND	ND	ND
Success FRS	2006-593-03	ND	ND	ND	ND	ND
TCS	2006-593-04	ND	ND	ND	ND	ND

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CDM Inc. DuraFlex
Original Premarket 510(K) Notification

6.3 SUBSTANTIAL EQUIVALENCE COMPARISON DISCUSSION

The DuraFlex material is a thermoplastic resin used to fabricate partial or full removable dentures, as well as occlusal splints and night guards. This material is substantially equivalent to Lucitone FRS Flexible Dental Resin manufactured by Dentsply International.

This material is commercially available in the United States. Both the device and the predicate device are thermoplastic resins with the same manufacturing processes and indications for use. The materials of the devices are reasonably identical. The device is comprised of (b)(4) resin while the predicate device is also composed of (b)(4) resin. The DuraFlex thermoplastic resin is substantially equivalent to Lucitone FRS Flexible Dental Resin. The fundamental characteristics are similar: the DuraFlex thermoplastic resin is similar in design, function, physical properties and intended use to the predicate device.

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

SECTION 7. 510(K) LABELING FOR PREDICATE DEVICE

The labeling for the predicate device is being submitted as a recommended advisory of the Premarket Notification 510(K).

7.1 LABELING FOR PREDICATE DEVICE

Reference 510(K) #K992956.

7.2 PACKAGE LABEL SAMPLE

Reference 510(K) # K992956.

7.3 INSTRUCTIONS FOR USE

Reference 510(K) # K992956.

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

SECTION 8. 510(K) STATEMENT OF INDICATIONS FOR USE

The 501(K) statement of indications for use for this device is being submitted in accordance with the requirements of 21 CFR 807.87.

8.1 STATEMENT OF INDICATIONS FOR USE.

The DuraFlex thermoplastic resin is used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

See next page for indications of use sheet.

Indications for Use

510(k) Number K063626

Device Name DuraFlex

Indications for use:

The DuraFlex thermoplastic resin is used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.
Dental Device Class II, 872.3760

Do not write below this line - Continue on another page if needed

Prescription Use
(Per 21 CFR 801.109)

OR

Over the counter

(Optional Format 1-2-96)

45



CDM Inc.
812 Water Ave NE
Albany OR 97321
Phone: 541-928-4444
Fax: 541-928-2444

510 (K) Summary

Submitter Name:	CDM Inc.
Submitter Address:	812 Water St NE Albany OR 97321
Submitter Telephone:	541-928-4444
Submitter Facsimile:	541-928-2444
Contact Person:	Bob Bowers Chief Operating Officer
Date Summary Prepared:	October 23, 2006

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

SECTION 9: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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.

9.1 SUBMITTER INFORMATION

- | | |
|---------------------------|---------------------------------------|
| a. Company Name: | CDM Inc. |
| b. Company Address: | 812 Water St NE
Albany OR 97321 |
| c. Company Telephone: | 541-928-4444 |
| Company Facsimile: | 541-928-2444 |
| d. Contact Person: | Bob Bowers
Chief Operating Officer |
| e. Date Summary Prepared: | October 23, 2006 |

9.2 DEVICE IDENTIFICATION

- | | |
|----------------------------|---|
| a. Trade/Proprietary Name: | DuraFlex |
| b. Classification Name: | Denture relining, repairing or rebasing resin.
21 CFR 872.3760 |

9.3 IDENTIFICATION OF PREDICATE DEVICES

The DuraFlex material is a thermoplastic resin used to fabricate partial or full removable dentures, as well as occlusal splints and night guards. This material is substantially equivalent to Lucitone FRS Flexible Dental Resin manufactured by Dentsply International. This material is commercially available in the United States.

9.4 DEVICE DESCRIPTION

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 the prostheses.

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

9.5 SUBSTANTIAL EQUIVALENCE

The DuraFlex thermoplastic resin is substantial equivalent to Lucitone FRS Flexible Dental Resin. The fundamental characteristics are similar: the DuraFlex thermoplastic resin is similar in design, function, physical properties and intended use to the predicate device.

9.6 INDICATIONS FOR USE

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.

9.7 TECHNOLOGICAL CHARACTERISTICS

Both the DuraFlex and the predicate device are similar in design, material characteristics, physical properties, handling characteristics, intended use and functionality.

CDM Inc. DuraFlex
Original Premarket 510(K) Notification

SECTION 10. 510(K) DEVICE COMPOSITION

The biocompatibility tests of this device are being submitted in accordance with the requirements of 21 CFR 807.87.

10.1 DEVICE MATERIAL COMPOSITION

The exact composition of the material is as follows: and an MSDS sheet is attached on pages 11-1 thru 11-3.

Material Composition:

Material is essentially composed of 99.9% DuraFlex (b)(4)

Resin with trace amounts of (b)(4) Material does not contain any hazardous substances.

Results of Hazardous Materials testing is attached Fig 10-1

10.2 MATERIAL DIFFERENCES

Both the device and the predicate device are thermoplastic resins with the same manufacturing processes and indications for use. The materials of the devices are identical. The device is comprised of (b)(4) resin while the predicate device is also composed of (b)(4) resin.

(b) (4)

(b) (4)

(b) (6)

10-2

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CDM Inc. DuraFlex
Original Premarket 510(K) Notification

11.1 DEVICE MATERIAL COMPOSITION MSDS FORM

Cosmetic Dental Materials Inc.
Materials Safety Data Sheet

(b)(4)

(b) (4)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Michael E. Adjeaha

Subject: 510(k) Number K063626/S1

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

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

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

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

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

Animal Tissue Source YES NO Material of Biological Origin YES NO

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

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 872.300, FBI, II Additional Product Code(s) with panel (optional):

Review: Susa Purser DE M, 2/8/07
(Branch Chief) (Branch Code) (Date)

Final Review: Susa Purser 2/8/07 4
(Division Director) (Date)

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K063626

Reviewer: Michael E. Adjodha
 Division/Branch: DAGID/DEDB
 Device Name: *DuraFlex*
 Products to Which Compared (510(K) Number If Known):
Lucitone FRS Flexible Dental Resin (K992956)

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	X		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		X ¹	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	X		If NO = Request Data
11. Data Demonstrate Equivalence?	X ²		Final Decision:SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

¹ No. Engineering bench testing needed

² Physical properties of device are equivalent to legally marketed devices.

DuraFlex, K063626, Cosmetic Dental Materials, Inc.

1. Intended Use: *DuraFlex*, a denture base resin material, is intended for use in the fabrication of full and partial dentures, occlusal splints, and night guards.

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

See attached Review Memorandum.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

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

ATTACH ADDITIONAL SUPPORTING INFORMATION



U.S. Department of Health and Human Services

Food and Drug Administration

REVIEW MEMORANDUM

Date: 08 February 2007
From: Michael E. Adjodha, Chemical Engineer, DAGID, HFZ-480
Subject: *DuraFlex* (K063626)
Cosmetic Dental Materials, Inc., Albany, Oregon
To: The record
Contact: Mr. Robert Bowers, Phone: 541-928-4444

I. BACKGROUND

Cosmetic Dental Materials, Inc., of Albany, Oregon, has submitted a Premarket Notification (510(k)) to introduce into U.S. interstate commerce *DuraFlex*, a denture base resin material. *DuraFlex*, a prescription Class II medical device, is classified as a "denture resin" under 21 CFR 872.3760.

DuraFlex is intended for use in the fabrication of full and partial dentures, occlusal splints, and night guards.

DuraFlex will be supplied in solid granule form. *DuraFlex* is a thermoplastic material that is intended to be heated, injection molded, and then cooled to achieve its finished form.

II. SUBMISSION CHANGES

By a facsimile dated January 23, 2007, the reviewer requested information on the composition of *DuraFlex*. The submitter responded by a letter dated January 29, 2007.

III. SUBMISSION SUMMARY

The formulation of *DuraFlex* consists of (b)(4) with trace amounts of (b)(4) selected from (b)(4)

The physical properties of *DuraFlex* include the following:

Tensile Strength:
Elastic Modulus:
Water Sorption:
Water Solubility:

(b)(4)

DuraFlex, K063626, Cosmetic Dental Materials, Inc.

DuraFlex will be provided as non-sterile. Biocompatibility test results were not reported for *DuraFlex*.

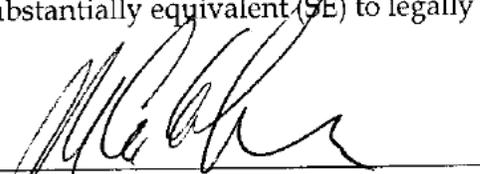
IV. REVIEWER'S ANALYSIS

(b)(4)

V. RECOMMENDATION

The information submitted by Cosmetic Dental Materials, Inc., demonstrates that *DuraFlex* (K063626) has the same indications and technological characteristics as a legally marketed device. *DuraFlex* is substantially equivalent (SE) to legally marketed denture base resins.

Primary Reviewer:


Michael E. Adjodha, M.ChE.
Chemical Engineer

Supervisory Reviewer:

Concur Do Not Concur
M. Susan Runner, DDS, MA
Chief, Dental Devices Branch

Internal Administrative Form

	YES	N
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		

10

From: Reviewer(s) - Name(s) Michael E. Adjoaha

Subject: 510(k) Number K063626

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

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

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

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

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

Animal Tissue Source YES NO Material of Biological Origin YES NO

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

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

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

Review: *Susan Runne* *DEDB* *1/23/07*
 (Branch Chief) (Branch Code) (Date)

Final Review: *Susan Runne* *1/23/07*
 (Division Director) (Date)

Revised: 4/2/03

DHHS/Food & Drug Administration
Center for Devices and Radiological Health
9200 Corporate Boulevard, HFZ-401
Rockville, MD 20850
Phone: 240-276-3688
240-276-3789



U.S. Department of Health and Human Services

Food and Drug Administration

FACSIMILE*

To: Mr. Robert Bowers

From: Michael E. Adjodha 

Fax: 541-928-2444

Pages: 1 (inc. cover)

Phone:

Date: 1/23/2007

Re: Additional Information for **DuraFlex (K063626)**

CC:

Urgent **For Review** **Please Comment** **Please Reply** **Please Recycle**

Dear Mr. Bowers,

In order to continue review of your 510(k) for **DuraFlex (K063626)** and to establish substantial equivalence to legally marketed devices following information is requested:

Chemical Composition:

- Please identify all colorants or other additives used in the formulation.

Performance Data:

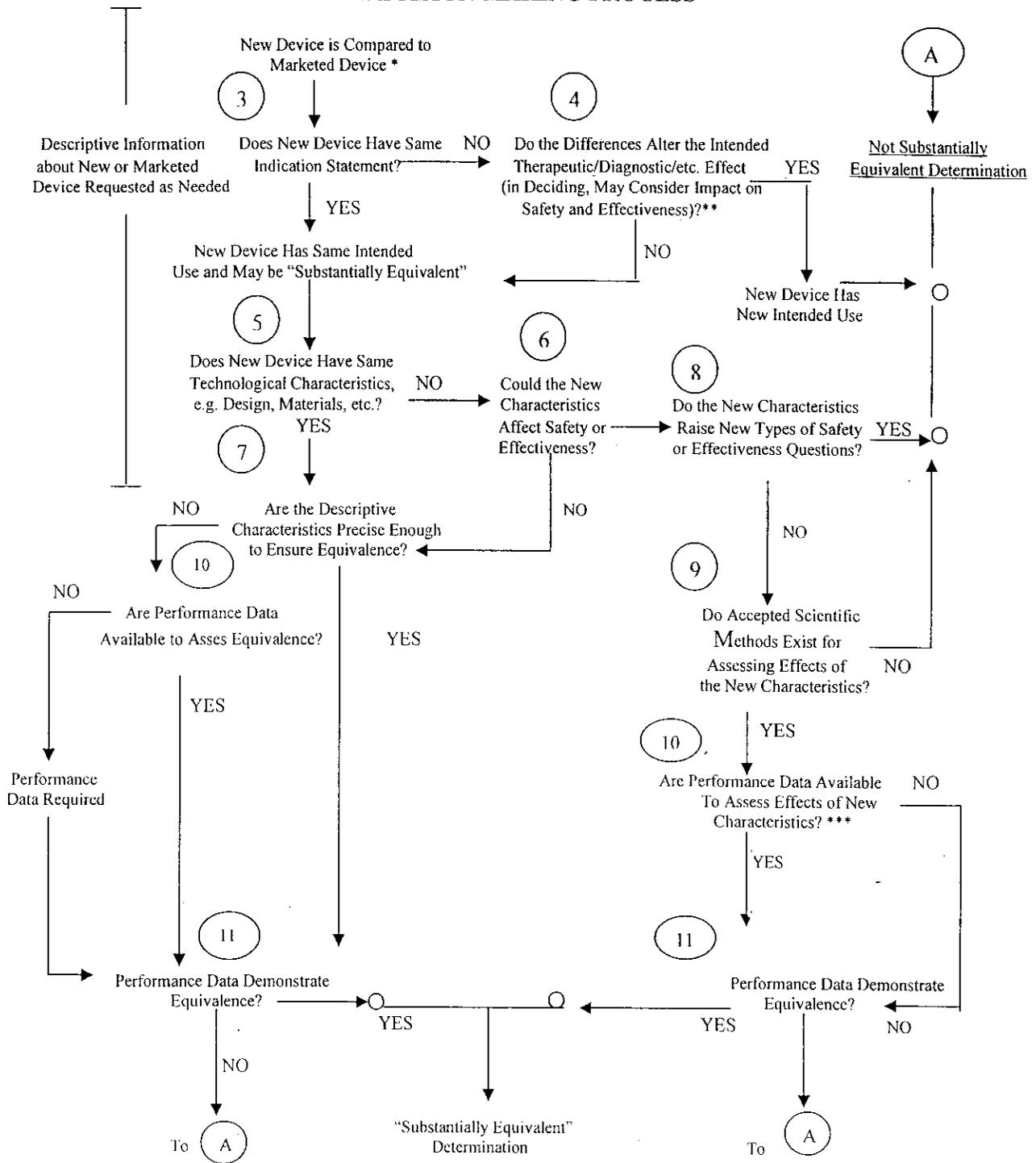
Please provide the following physical properties (per ISO 1567:1999):

- Flexural Strength (MPa)
- Flexural Modulus (GPa)
- Water Sorption ($\mu\text{g}/\text{mm}^3$)
- Water Solubility ($\mu\text{g}/\text{mm}^3$)

Please fax your **complete** response to **Michael Adjodha (240-276-3789)** and mail a **hard copy** to the **Document Mail Center** at the address above. **Your document will be placed on hold. Incomplete responses will not remove the hold status.** Review of your application will resume once a complete response to the above information has been submitted. Please call me at **240-276-3688** if you have any questions. Thank you.

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on content of the communication is not authorized. **IF YOU RECEIVED THIS DOCUMENT IN ERROR, PLEASE IMMEDIATELY NOTIFY US BY PHONE AND RETURN IT TO US BY MAIL AT THE ABOVE ADDRESS.** Thank you.

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



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

A

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		/
3. Have you verified that the Document is labeled Class III for GMP purposes?		/
4. If, not, has POS been notified?		/
5. Is the product a device?	/	
6. Is the device exempt from 510(k) by regulation or policy?	/	/
7. Is the device subject to review by CDRH?	/	
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		/
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		/
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		/

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K063626

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

- * - May not be applicable for Special 510(k)s.
- ** - Required for Class III devices, only.
- *** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No

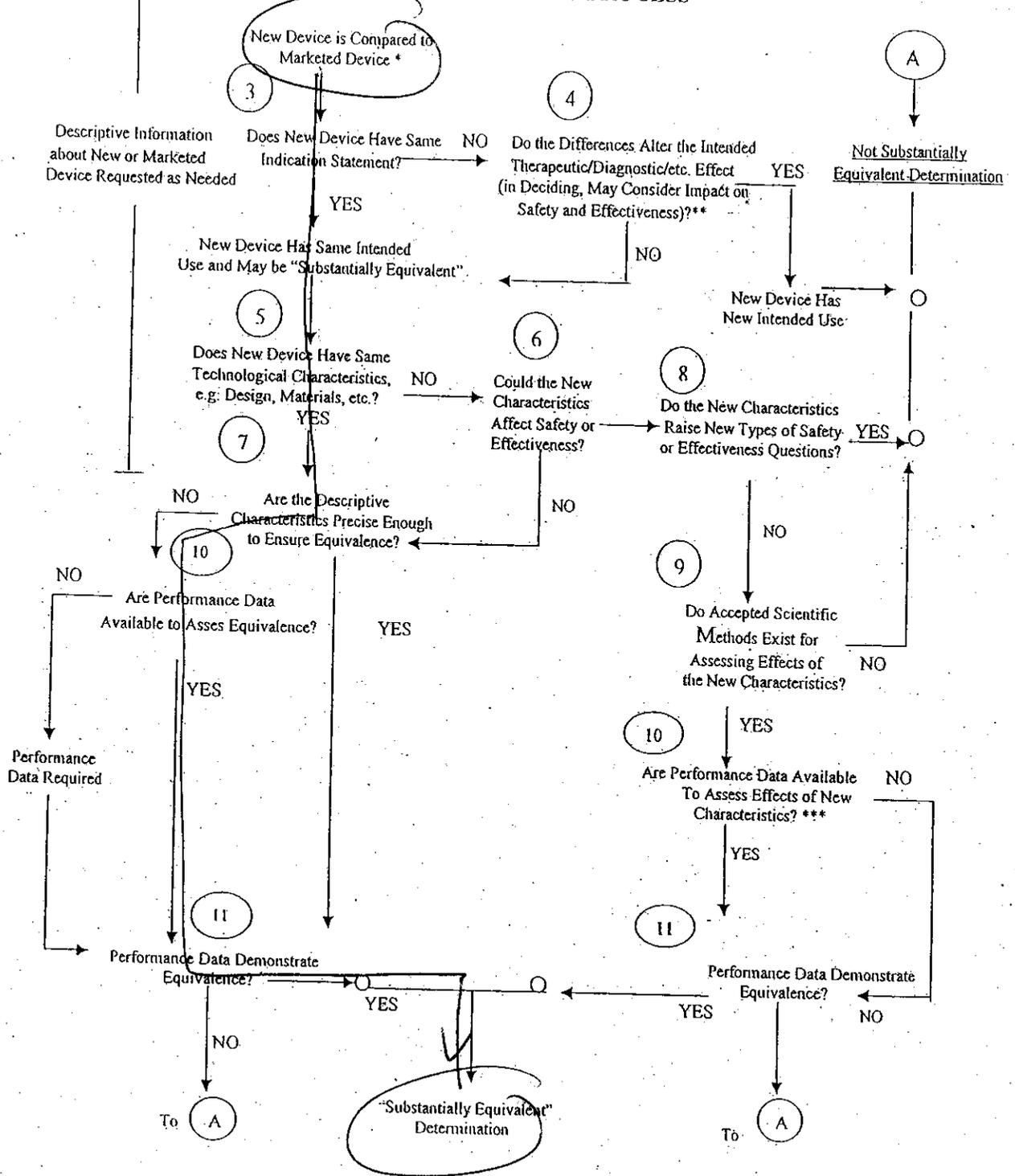
Reviewer: _____

Concurrence by Review Branch: _____

Date: DEC - 7 2006

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

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



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

5

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

February 05, 2007

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

COSMETIC DENTAL MATERIALS INC
812 WATER ST. N.E.
ALBANY, OR 97321
ATTN: ROBERT BOWERS

510(k) Number: K063626
Product: DURAFLEX

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

K063626/S1

CDM Inc. DuraFlex
Original Premarket 510(K) Notification **K063626**

510(K) Addition Information Response K063626

January 29, 2007

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

Dear Sir:

Enclosed is the requested additional information for pending 510(K) number **K063626**. As per phone conversations with FDA representative Michael Adjodha, I believe this response is correct and complete and I look forward to hearing from you. I will be the contact person for the manufacturer, my contact information is:

Robert Bowers c/o
CDM Inc.
812 Water Ave NE

Tel: (541)928-4444
Fax: (541)928-2444

Thank you,

Robert Bowers,
Chief Operations Officer
CDM Inc.

K-32

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100-100-100

CDM Inc. DuraFlex
Original Premarket 510(K) Notification **K063626**

510(K) Addition Information Response K063626

Response Section 1.1 Chemical Composition

(b)(4)

Response Section 1.2 Physical Properties

Physical Properties per ISO 1567:1999

Tensile strength	ASTM D-638
Tensile E-modulus	ASTM D-790
Water absorption	
Solubility in water	

(b)(4)

Response Section 1.3 Other Information

(b)(4) 3rd Party Testing