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Heraeus Kulzer, Inc.

Product Name: Flexitime Bite

510(K) Pre-Market Notification Submission

DEC 05 2008

510(K) Summary & Clinical Evaluation

Reference the enclosed documents:

Summary of Safety and Effectiveness of Flexitime Bite (Project No.: D922)

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7

Heraeus Kulzer GmbH · Alte Heerstraße · 41538 Dormagen

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Dentistry Division
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Your reference:
Our reference: Statement Flexitime bite
function new
Your correspondence of:

9 June 2008

Summary of Safety and Effectiveness of Flexitime Bite (Project No.: D922)

1. Description and Intended Use of the Medical Device:

The product is developed under the project name D 922. Flexitime bite is a scannable polyvinyl siloxane for bite registration with superior hardness and a very short application time in mouth. Its surface properties and optimised colour enable it to be optically recorded in CAD/CAM systems to portray the antagonists. Flexitime Bite can be scanned in the Heraeus scanner and many other CAD/CAM systems.

2. Indication List:

Flexitime bite is intended for the following application:

- Standard bite registrations in the end bite position
- Portrayal of antagonists
- Coating of bite forks
- Key material for needle point registration
- Production of small model segments

Page 2

3. Toxicological Evaluation:

In accordance with the European Medical Device Directive 93/42/EEC and national medical device legislation a medical device is required to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes an evaluation of biocompatibility in accordance with EN ISO 10993-1.

The biocompatibility of the new Flexitime Bite prototype was verified in accordance with the international standard. The biocompatibility of Flexitime Bite was documented in a Biological Evaluation Report and the benefit/risk outweighed the possible risks with the new catalyst. (Biological Evaluation Report (Biocompatibility) for Flexitime Bite (Hecker, Troesken, 19. May 2008). In addition toxicological expert opinions are carried out to assess possible risks by using Flexitime Bite as bite registration material and to evaluate recommendations for appropriate warnings. These risk assessments and recommendations have been taken into account in the instruction for use and in the clinical evaluation.

4. Physical Properties and Compliance with ISO 13903:

The physical data for the new Flexitime Bite are in accordance with the functional specification for D 922 and the requirements of ISO 13903.

5. Clinical Evaluation:

The new Flexitime Bite is a bite registration material which is in general classified as a class I medical device under the Medical Device Directive 93/42/EEC.

- Flexitime Bite represents a well-known type of bite registration material which has proven to exhibit the expected performance and clinical effectiveness.
- There is no hint for undesirable effects and potential risks when Flexitime Bite is applied according to the instructions for use.

Considering the evaluated data and technical results for Flexitime Bite it is concluded that the product exhibits the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable when weighed against their benefits in dentistry. Therefore a positive risks versus benefits ratio was stated by the expert for Flexitime Bite (clinical evaluation report according to MEDDEV 2.7.1. for Flexitime Bite, Hecker, 06.06.2008)

K082591

9

6. Summarized Evaluation:

The physical properties meet the requirements of the functional specification and ISO 13903. The biocompatibility of Flexitime Bite was tested according to the requirements of EN ISO 10993 and additional toxicological expert opinions have been carried out. Based upon these results and the above mentioned clinical evaluation it is concluded that the product can be expected to exhibit the claimed performance and that potential undesirable clinical effects and risks seem well controlled and acceptable when weighed against their benefit in dentistry.

The risk analysis according to EN ISO 14971 which was carried out for Flexitime Bite showed that the application of Flexitime Bite according to the manufacturer's instructions for use shows an acceptable risk.

Flexitime Bite meets all relevant requirements for scannable polyvinyl siloxane bite registration material in accordance with the European Medical Device Directive 93/42/EEC and national medical device legislation. Based on the actual facts Flexitime Bite is considered to be effective and safe when using it in accordance with the manufacturer's information for use.

Annegrete Wegner

Date:

Signature:

Release:

Dr. Martina Hecker

Date: 13. June 2008 Signature





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 05 2008

Ms. Cheryl V. Zimmerman
Director, Quality Assurance & Regulatory Affairs
Heraeus Kulzer, Incorporated
4315 South Lafayette Boulevard
South Bend, Indiana 46614-2517

Re: K082591
Trade/Device Name: Flexitime Bite
Regulation Number: 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: September 5, 2008
Received: September 8, 2008

Dear Ms. Zimmerman:

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

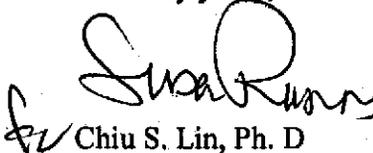
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,


for Chiu S. Lin, Ph. D

Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082591

5

Page 1 of 1

510(k) Number (if Known):

Device Name: Flexitime Bite

Indications For Use:

Flexitime Bite is an addition-cross-linking polyvinyl siloxane with a very high final Shore D hardness of 40. Its surface properties and optimized color enable it to be optically recorded in CAD/CAM systems to portray the antagonists.

Used for standards bite registrations in the end bite position

Coating of bite forks

Key material for needle point registration

Production of small model segments.

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

Concurrence of CDRH, Office of Device evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use



(Optional Format 1-2-96)

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082591