K091494

Heraeus Kulzer, LLC
Product Name: Flexitime Light Flow / Medium Flow
510(k) Pre-Market Notification Submission

I. GENERAL INFORMATION

Date: May 12, 2009

Submitter: Cheryl V. Zimmerman
300 Heraeus Way
South Bend, Indiana 46614

JUL 31 2009

Telephone No.: 574-299-5444

Fax No.: 574-291-2542

Submitter's Company Establishment Number: 1925223

Submitter's Company Name: Heraeus Kulzer, LLC

Device Trade Name: Flexitime Flow

Device Common Name: Dental Impression Material

Original 510(k) No.: Not Applicable

Manufacturer: Heraeus Kulzer, GmbH
Hanau, Germany

Device Classification: Class II – Dental Impression Material. 21 CFR Part 872.3660

Device Product Code: 76ELW

Reason for Submission: This submission is being made to request approval to market Flexitime Flow.

Statement of Substantial Equivalence: Flexitime Light Flow /Medium Flow is equivalent to Flexitme Magnum 360 K000629 and K003930.

Compliance with requirements of Performance Standards: No performance standards have been established for this type of device. The results of device performance testing demonstrated that it is suitable for use as an impression material, Flexitime Flow has been designed and manufactured to perform in a manner substantially equivalent to that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2009

Ms. Cheryl V. Zimmerman
Manager, Quality Operations and Compliance
Heraeus Kulzer, Incorporated
300 Heraeus Way
South Bend, Indiana 46614

Re: K091494
Trade/Device Name: Flexitime Light Flow and Flexitime Medium Flow
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: May 15, 2009
Received: May 20, 2009

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.

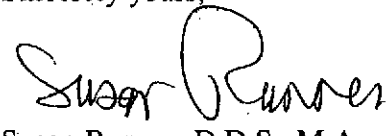
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): K091494

Device Name: *Flexitime Light Flow / Medium Flow*

Indications For Use:

Flexitime Light Flow/Flexitime Medium Flow each is an addition-cross-linking polyvinyl siloxane impression material for all inlay, crown and bridge, edentulous and partial impressions.

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

Concurrence of CDRH, Office of Device evaluation (ODE)

Prescription Use V OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number: K091494