K113574

ATTACHMENT 3

JUL 13 2012

510(k) Summary — Revised 2/20/12

510(k) summary of safety and effectiveness information for Flexitime Monophase Pro Scan

1. **Submitter Information**

Company Name: Heraeus Kulzer, LLC
Company Address: 300 Heraeus Kulzer, LLC
South Bend, IN

Company Phone: (574) 299-5400

Contact Person: Chris Holden

Date Summary prepared: November 2, 2011(Revised February 20, 2012)

2. **Legally Market Devices to which Substantial Equivalence is claimed:**

Heraeus Kulzer, GmBH - Flexitime Fast & Scan K102770
Heraeus Kulzer, GmBH - Flexitime Monophase K000629

3. **Device Identification**

Trade /Proprietary Name:	Flextime Monophase Pro Scan
Common Name:	Impression Material (21 CFR 872.3660)
Classification:	Class II
FDA Code:	Dental ELW

4. **Device Description**

Flexitime Monophase Pro Scan is an addition-cross-linking polyvinyl siloxane impression material. Flexitime Monophase Pro Scan is delivered in 380 ml cartridges and is part of the Flexitime Dynamix System. Flexitime Monophase Pro Scan is characterized by the addition of a scannable dye (for scannability). Flexitime Monophase Pro Scan was developed to complement Flexitime Monophase regarding scannability and shore hardness, thus improving the impression taking especially for dental implants. Additionally the hydrophilic characteristics for optimal impression taking in the wet surroundings combined with good mechanical properties should be ensured. The mouth retention time for the product is 2.5 minutes.

Flexitime Monophase Pro Scan is for use in the Dynamix automatic dispensing and mixing system.

5. **Intended Use**

Flexitime Monophase Pro Scan is used to get an exact negative copy of the patient's dental situation and can be used for optical scanning in dental scanners designed for scanning impression materials.

6. **Technological Characteristics**

The physical properties of Flexitime Monophase Pro Scan like Flexitime Fast and Scan (K102770) and Flexitime Monophase (K000629) are in compliance with ISO 4823.

Both Flexitime Monophase Pro Scan and Flexitime Fast and Scan (K102770) are prepared without requiring additional surface treatment for optical scanner in dental scanners designed for scanning impression materials.

7. **Nonclinical Testing**

The biological compatibility of Flexitime Monophase Pro Scan was verified in accordance with the international standards.

The biocompatibility of Flexitime Monophase Pro Scan in the aforementioned indication was documented in a biocompatibility evaluation report and the benefit/risk relation has been judged as positive.

Considering the evaluated scientific data and technical results for Flexitime Monophase Pro Scan it is concluded that the products can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and accepted, when weighed against their benefit to dentistry. Therefore, a positive benefit versus risk ratio can be stated by the experts for Flexitime Monophase Pro Scan, provided that the products applied in accordance with its intended use as outlined in the manufacturer's instructions for use.

8. **Summary of Conclusion**

Flexitime Monophase Pro Scan is substantially equivalent to Flexitime Fast & Scan and Flexitime Monophase. All of the products are indicated for taking impression materials of suited techniques. In addition, Flexitime Monophase Pro Scan is scannable without prior preparation as is required with the predicate device Flexitime Fast and Scan.

A biocompatibility evaluation has been performed by a toxicologist for Flexitime Monophase Pro Scan and it was confirmed that the product meets the requirements of ISO 10993 Standard and it is concluded that the safety of Flexitime Monophase Pro Scan is equivalent to that of the predicate devices.

The risk analysis was carried out for Flexitime Monophase Pro Scan and it is concluded that the safety of the Flexitime Monophase Pro Scan device for the intended use is substantially equivalent to the predicate devices. Flexitime Monophase Pro Scan and the predicate devices both have the same indications for use, warnings and contraindications. When used in accordance with the instructions for use, by qualified personnel, Flexitime Monophase Pro Scan is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Jamie L. Mearna
Quality Assurance & Regulatory Affairs
Heraeus Kulzer, LLC
300 Heraeus Way
South Bend, Indiana 46614

JUL 13 2012

Re: K113574
Trade/Device Name: Flexitime Monophase Pro Scan
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: May 31, 2012
Received: July 11, 2012

Dear Ms. Mearna:

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.

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/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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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 (if known): K113574

Device Name: Flexitime Monophase Pro Scan

Indications for use:

It is used to get an exact negative copy of the patient's dental situation and can be used for optical scanning in dental scanners designed for scanning impression material.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K113574