K091635

Heraeus

SEP - 3 2009

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Your reference:
Our reference: Statement Venus Diamond flow
Your correspondence of:

Heraeus Kulzer GmbH · Alte Heerstraße · 41538 Dormagen

To whom it may concern

May 08, 2009

Summary of Safety and Effectiveness of
Venus Diamond Flow (Project Name NEFL)

Description and Intended Use of the Medical Device:
The product is developed under the project name NEFL / D913.

Venus Diamond flow is a flowable, light-cured radiopaque nano-hybrid composite used for adhesive, tooth-coloured anterior and posteriors restorations.

Indication List:

Venus Diamond flow is intended for the following application:

- Enlarged fissure sealing
- Cavity lining – as the first layer for class I and class II cavities.
- Class V fillings
- Minimally invasive Class I and II fillings in areas not subjected to masticatory forces
- Minimally invasive Class III fillings
- Small repairs of direct and indirect restorations combined with a suitable bonding agent
- Interlocking of loosened teeth

Toxicological Evaluation:

In accordance with the Medical Device Directive 93/42/EWG and national European 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-ff.

The biocompatibility of the Venus Diamond flow was verified in accordance with the international standard. The biocompatibility of Venus Diamond flow was documented in a Biological Evaluation Report and the benefit/risk overweighed the possible risks with the new flowable composite when the product is used according to the intended use written in the instruction for use. (Biological Evaluation Report (Biocompatibility) for Venus Diamond flow. (Hecker, Troesken, Utterodt January 21,2009).

Physical Properties and Compliance with DIN EN 4049:2000:

The physical data for the new Venus Diamond flow are in accordance with the functional specification for VENUS Diamond flow/NEFL and the requirements of DIN EN 4049.

Clinical Evaluation:

The new Venus Diamond flow material which is classified as a class IIa medical device under the Medical Device Directive 93/42/EEC.

- Venus Diamond flow represents a well-known type of restoration material which has proven to exhibit the expected performance and clinical effectiveness.
- There is no hint for undesirable effects and potential risks when Venus Diamond flow is applied according to the instruction for use.

Considering the evaluated data and technical results for Venus Diamond flow 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 the positive risk versus benefits ratio was stated by the expert for Venus Diamond flow. (Clinical evaluation Report according to MEDDEV 2.7.1. for Venus Diamond flow. (Hecker, Troesken, Utterodt January 21, 2009 and April 28, 2009)

Summarized Evaluation:

The physical properties meet the requirements of the functional specification and DIN EN 4049. The biocompatibility of Venus Diamond flow was tested according to the requirements of EN ISO 10993ff. 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 was carried out for Venus Diamond flow showed that the application of Venus Diamond flow according to the manufacturer's instruction for use shows an acceptable risk.

The Venus Diamond flow meets all relevant requirements for Polymer based filling restorative and luting materials in accordance with the Medical Device Directive 93/42/EEC and national European medical device legislation. Based on the actual facts Venus Diamond flow is considered to be effective and safe when using it in accordance with the manufacturer's information for use.

Annegrete Wegner Date: 08.05.09 Signature: Annegrete Wegner

Release:

Dr. Andreas Utterodt Date: 08.05.09 Signature

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Cheryl V. Zimmerman
Director Quality Assurance & Regulatory Affairs
Heraeus Kulzer, LLC
300 Heraeus Way
South Bend, Indiana 46614

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Re: K091635
Trade/Device Name: Venus Diamond Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF, EBC, and LBH
Dated: August 26, 2009
Received: August 28, 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.

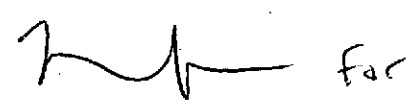
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 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): K091635
Device Name: **VENUS DIAMOND FLOW**
Indications for Use:

- Enlarged fissure sealing
- Cavity lining - as the first layer for Class I and II cavities
- Class V fillings
- Minimally invasive Class I and II fillings in areas not subjected to masticatory forces
- Minimally invasive Class III fillings
- Small repairs of direct and indirect restorations combined with a suitable bonding agent
- Interlocking of loosened teeth

Prescription Use ___/___ 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)

Kevin Mulay for MSP

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

510(k) Number: K091635