



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 30 2003

Ms. Cheryl V. Zimmerman  
Manager, Quality Operations and Compliance  
Heraeus Kulzer, Incorporated  
4315 South Lafayette Boulevard  
South Bend, Indiana 46614

Re: K033665  
Trade/Device Name: Venus™ Flow  
Regulation Number: 21 CFR 872.3690  
Regulation Name: Tooth Shade Resin Material  
Regulatory Class: II  
Product Code: EBF  
Dated: November 19, 2003  
Received: November 24, 2003

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 Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

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510(k) Number (if Known): K033665

Device Name: Venus Flow

Indications For Use:

Venus flow is a flowable, light curing, radiopaque hybrid composite used for adhesive, tooth-colored anterior and posterior restorations. Due to its low viscosity Venus Flow provides excellent coverage tooth structure.

Applicable applications includes:

Baseliner in Class I & II cavities; Fissure sealing; Enlarged fissure sealing; Class V fillings; Minimally invasive Class I and II fillings in areas not subjected to masticatory forces; Minimally invasive Class III fillings; Smaller contour and shade adjustment on the enamel and dentine; Small surface repairs to direct and indirect restorative in combination with a suitable bonding agent; Splinting teeth; Cavity lining; Bracket retention; Sealing endodontically treated teeth; Luting porcelain or composite veneers; Filling in voids in temporary crown and bridges materials

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

Concurrence of CDRH, Office of Device evaluation (ODE)

Angela Blackwell for NSK

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

510(k) Number: K033665

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

(Optional Format 1-2-96)