K072150

510(k) SUMMARY

SEP 13 2007

Confi-Dental Products Co.
416 So. Taylor Ave.
Louisville, CO 80027

Date prepared: July 2007
Contact: Steve Rudolph

Name: Dimer Acid Derived Nanohybrid Composite
Classification name: Tooth shade resin material, 872.3690
Predicate devices: Crystalline L3 Multiuse hybrid K946307
3M Brand restorative K920425
Grandio K051867

Device description:
Dimer acid derived nanohybrid composite is for use in all dental cavity classes. The composite is a single light cured paste with a different monomer system chemistry than other filling composites that are currently available. The new resin system produces exceptionally high conversion values with a very low shrinkage.

Intended use:
Dimer acid derived nanohybrid composite is indicated for class I, II, III, IV and V cavity classes.

Substantial equivalence:
Dimer acid derived nanohybrid composite is substantially equivalent to other legally marketed devices in the United States. A comparison of the performance data and indications for use to predicate devices indicates that the dimer acid derived nanohybrid composite functions in a manner similar to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2007

Novocol, Incorporated
C/O Mr. Steven Rudolph
Quality Assurance/ Regulatory Affairs Manager
Confi-Dental Products Company
416 South Taylor Avenue
Louisville, Colorado 80027

Re: K072150
Trade/Device Name: Dimer Acid Derived Nanohybrid Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: August 2, 2007
Received: August 6, 2007

Dear Mr. Rudolph:

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 (240) 276-0115. 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 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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): K072150

Device Name: Dimer Acid Derived Nanohybrid Composite

Indications for Use:

"Dimer Acid Derived Nanohybrid Composite" is a light cure restorative material indicated for direct esthetic restoration of anterior and posterior teeth. It provides simple esthetics since it is formulated in shades matching the VITA Lumin Shade guide. This low shrinkage nanohybrid composite can be used in all classes of direct dental restorations, Class I, II, III, IV, and V.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ion Sign-Off)
...sion of Anesthesiolo... ...eneral Hospital,
...ection Control, Dental Devices
...Number: K072150