K130672

Section IV

510(k) Summary

Submitter:
Pac-Dent International, Inc.
21038 Commerce Point Dr.
Walnut, CA91789

AUG 13 2013

Contact Person:
Wenying Zhu
Materials Scientist
909-839-0888 ext.111

Date Summary Prepared:
January 2013

Device Name

Trade Name: OptiFlow II Flowable Composite, LC
Common Name: Flowable light cure provisional add-on material
Classification Name: Tooth shade Resin Material, per 21 CFR 872.3690

Predicate Device

Filtek™ Supreme Ultra Flowable Restorative (K100235)

Description of Device

OptiFlow II Flowable Composite, LC is a light cure resin-based flowable restorative dental composites. The restorative is packaged in capsules and syringes. The fillers are a combination of radiopaque inorganic fillers and advanced nano-silicas with an average particle size of 0.7 microns to produce a loading approximately 57% by weight (40% by volume). All shades have a radiopacity of 200%.

Indications for Use

Repair of minimally invasive cavity (including non-stress bearing areas)
Pit and fissure sealant

Class III-V restorations
Repair of porcelain restorations
Repair of ceramic/composite veneers

Summary of Biocompatibility Tests

OptiFlow II Flowable Composite, LC is substantially equivalent to the predicate device Filtek™ Supreme Ultra Flowable Restorative in terms of materials and technological properties. It is also substantially equivalent to CuRAY Match Paint-On Composite Restor (K833810) which is produced by the same manufacturer in terms of manufacturing process. No biocompatibility test is required to establish substantial equivalence for OptiFlow II Flowable Composite, LC.

Summary of Physical Tests

This 510(k) submission includes data from bench testing to evaluate the performance of OptiFlow II Flowable Composite compared to predicate device Filtek™ Supreme Ultra Flowable Restorative. Properties evaluated include Flexural Strength, Young's Modulus, Compressive Strength, Diametral Tensile Strength and Rockwell Hardness.

Substantial Equivalence

OptiFlow II Flowable Composite, LC is substantially equivalent to the predicate device Filtek™ Supreme Ultra Flowable Restorative in terms of indications for use, composition of materials and physical properties. Physical properties evaluated include Flexural Strength, Young's Modulus, Compressive Strength, Diametral Tensile Strength and Rockwell Hardness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 13, 2013

Pac-Dent International, Incorporated
C/O Dr. Wenying Zhu
Materials Scientist
21038 Commerce Point Drive
Walnut, CA 91789

Re: K130672
Trade/Device Name: OptiFlow II Flowable Composite, LC
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: May 29, 2013
Received: June 4, 2013

Dear Dr. Zhu:

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 contact 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. 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.

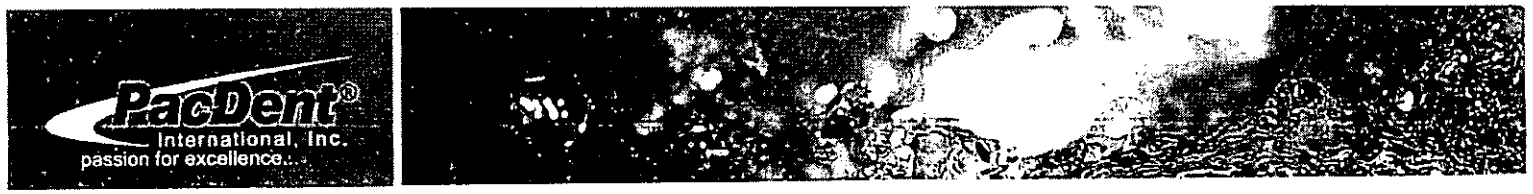
You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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Section III

Indications for Use Statement

510(k) Number (if known): K130672

Device Name: OptiFlow II Flowable Composite, LC

Indications for Use:

OptiFlow II Flowable Composite, LC is intended for use as:

- Repair of minimally invasive cavity (including non-stress bearing areas)
- Pit and fissure sealant
- Class III-V restorations
- Repair of porcelain restorations
- Repair of ceramic/composite veneers

Prescription Use X OR Over-The-Counter Use _____

Sheena A. Green -S
2013.08.07 10:29:43 -04'00'
for M. Susan Runner, DDs, MA

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

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