K083610

3M ESPE

5. 510(k) Summary

DEC 17 2008

3M ESPE
Dental Products

3M Center
St. Paul, MN 55144-1000
651 733 1110

3M ESPE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter..... 3M Company
3M ESPE Dental Products
3M Center, Bldg. 275-2W-08
St. Paul, MN 55144-1000 USA
Establishment Registration Number: 2110898

Contact person..... Scott Erickson
Regulatory Affairs Specialist
Phone: (651) 736-9883
Fax: (651) 736-1599
sterickson@mmm.com

Date Summary was Prepared..... 12/05/2008

Trade Name..... Filtek™ Supreme Ultra Universal Restorative

Common Name(s)..... Tooth shade resin material

Recommended Classification..... Tooth shade resin material
(21 CFR 872.3690,
Product Code: EBF)

Predicate Devices:
3M™ ESPE™ HAUR

Description of Device:
Filtek™ Supreme Ultra Universal Restorative is a visible-light activated, radiopaque, restorative composite.

Indications for Use:
- Direct anterior and posterior restorations (including occlusal surfaces)
- Core Build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers

Substantial Equivalence:
Information provided in this 510(k) submission shows that Filtek ™ Supreme Ultra Universal Restorative is substantially equivalent to the predicate device 3M™ ESPE™ HAUR in terms of intended use, indications for use, composition, physical properties and technological characteristics. A biocompatibility assessment was developed for Filtek™ Supreme Ultra Universal Restorative using standard risk assessment techniques and consideration of FDA & internationally recognized guidelines. The conclusion of the assessment is that Filtek™ Supreme Ultra Universal Restorative is safe for its intended use.

This 510(k) submission includes data from bench testing to evaluate the performance of Filtek™ Supreme Ultra Universal Restorative compared to predicate device 3M™ ESPE™ HAUR. The properties evaluated include Compressive strength, Diametral Tensile Strength, Flexural strength, Flexural Modulus, Surface hardness, Radio-opacity, Water Sorption, Water Solubility, Polish Retention and Fluorescence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Scott Erickson
Regulatory Affairs Specialist
3M Company
3M ESPE Dental Products
3M Center, Building 275-2W-08
St. Paul, Minnesota 55144-1000

DEC 17 2008

Re: K083610
Trade/Device Name: Filtek™ Supreme Ultra Universal Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: December 5, 2008
Received: December 8, 2008

Dear Mr. Erickson:

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.

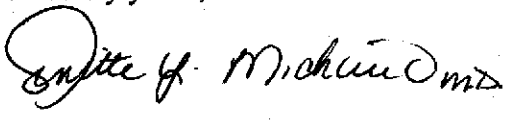
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3M ESPE

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K083610

Device Name: Filtek™ Supreme Ultra Universal Restorative

Indications for Use:

- Direct anterior and posterior restorations (including occlusal surfaces)
- Core Build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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