3M ESPE

K100235

5. 510(k) Summary

3M ESPE
Dental Products

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

MAY 12 2010

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
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Date Summary was Prepared..... January 25, 2010

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

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

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

Predicate Devices:
3M™ LVR System, Revolution Formula 2

Indications for Use:
- Class III and V restorations
- Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations)
- Base/liner under direct restorations
- Repair of small defects in esthetic indirect restorations
- Pit and fissure sealant
- Undercut blockout
- Repair of resin and acrylic temporary materials

Description of Device:
Filtek Supreme Ultra Flowable Restorative, is a low viscosity, visible-light activated, radiopaque, flowable nanocomposite. The restorative is packaged in capsules and syringes. It is available in a variety of tooth-colored shades. The shades offered with Filtek Supreme Ultra flowable restorative were designed to coordinate with shades offered with Filtek™ Supreme Ultra Universal Restorative. Filtek Supreme Ultra flowable restorative contains bisGMA, TEGDMA and Procrylat resins. The fillers are a combination of ytterbium trifluoride filler with a range of particles sizes from 0.1 to 5.0 microns, a non-agglomerated/non-aggregated surface modified 20nm silica filler, a non-agglomerated/non-aggregated surface modified 75nm silica filler, and a surface modified aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles). The aggregate has an average cluster particle size of 0.6 to 10 microns. The inorganic filler loading is approximately 65% by weight (46% by volume).

Filtek™ Supreme Ultra Flowable Restorative is a minor modification of predicate device 3M™ LVR System. The formulation was modified to improve physical properties, such as fluorescence and polish retention and to provide additional tooth colored shades of the restorative material.

When irradiated by light, the methacrylate functionalities of the resins and surface-treated fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.

Technological Characteristics:
Filtek Supreme Ultra flowable restorative contains bisGMA, TEGDMA and Procrylat resins. The fillers are a combination of ytterbium trifluoride filler with a range of particles sizes from 0.1 to 5.0 microns, a non-agglomerated/non-aggregated surface modified 20nm silica filler, a non-agglomerated/non-aggregated surface modified 75nm silica filler, and a surface modified aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles). The aggregate has an average

cluster particle size of 0.6 to 10 microns. The inorganic filler loading is approximately 65% by weight (46% by volume).

When irradiated by light, the methacrylate functionalities of the resins and surface-treated fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.

Filtek™ Supreme Ultra Flowable Restorative is a minor modification of predicate device 3M™ LVR System. The formulation was modified to improve physical properties, such as fluorescence and polish retention and to provide additional tooth colored shades of the restorative material. As a result of the reformulation, a biocompatibility assessment was developed for Filtek™ Supreme Ultra Flowable Restorative using standard risk assessment techniques and consideration of FDA & internationally recognized guidelines, including ISO 10993 Parts 3, 5, 6, 10 and 11. The conclusion of the assessment is that Filtek™ Supreme Ultra Flowable Restorative is safe for its intended use.

Summary of Physical Tests:
This 510(k) submission includes data from bench testing to evaluate the performance of Filtek™ Supreme Ultra Flowable Restorative compared to predicate devices 3M™ LVR System and Revolution Formula 2. Properties evaluated include Compressive Strength, Diametral Tensile Strength, Flexural Strength, Flexural Modulus, Surface Hardness, Radiopacity, Water Sorption, Water Solubility, Polymerization Shrinkage, Polish Retention and Fluorescence.

Substantial Equivalence:
Information provided in this 510(k) submission shows that Filtek™ Supreme Ultra Flowable Restorative is substantially equivalent to the predicate device 3M™ LVR System in terms of intended use, indications for use, composition, physical properties and technological characteristics. Filtek™ Supreme Ultra Flowable Restorative is substantially equivalent to the predicate device Revolution Formula 2 in terms of intended use, indications for use, physical properties and technological characteristics. Physical properties evaluated include Compressive Strength, Diametral Tensile Strength, Flexural Strength, Flexural Modulus, Surface Hardness, Radiopacity, Water Sorption, Water Solubility, Polymerization Shrinkage, Polish Retention and Fluorescence. A comparison of technological characteristics is provided below:

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Technological property	Filtek™ Supreme Ultra Flowable	3M™ LVR	Revolution Formula 2
Camphorquinone/amine photoinitiator system	X	X	-
Methacrylate-based resin matrix	X	X	X
Silane treated fillers	X	X	-
Bonded with a permanent dental adhesive	X	X	X
When irradiated by light, the methacrylate functionalities of the resins and surface-treated fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.	X	X	X

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

MAY 12 2010

Re: K100235
Trade/Device Name: Filtek ™ Supreme Ultra Flowable Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: April 23, 2010
Received: April 27, 2010

Dear Mr. Scott 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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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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4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K100235

Device Name: Filtek™ Supreme Ultra Flowable Restorative

Indications for Use:

- Class III and V restorations
- Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations)
- Base/liner under direct restorations
- Repair of small defects in esthetic indirect restorations
- Pit and fissure sealant
- Undercut blockout
- Repair of resin and acrylic temporary materials

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)

Kevin Mudd for HLS R
Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices