

K072733

REF 15

3M ESPE

5. 510(k) Summary

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. 260-2A-11
St. Paul, MN 55144-1000 USA
Establishment Registration Number:
2110898

Contact person..... Scott Erickson
Regulatory Affairs Specialist
Phone: (615) 736-9883
Fax: (651) 737-6049
sterickson@mmm.com

Date Summary was Prepared..... 9/26/07

Trade Name..... 3M™ ESPE™ Adult Crown

Common Name(s)..... Preformed composite crown

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

Predicate Devices:
Sinfony™ Indirect Lab Composite
Paradigm™ MZ100 Block for CEREC®
3M LVR System
Z100™ Restorative,
3M™ ESPE™ HAUR
P-10™ Posterior Filling Material

Description of Device:

3M™ ESPE™ Adult Crown is a tooth colored single unit crown for use as a durable restoration for permanent teeth. This preformed composite crown, manufactured by 3M ESPE, is initially malleable and can be easily customized to the crown preparation by trimming and reshaping. The crown is then light-cured to obtain its high strength and subsequently cemented in place with permanent cement. The entire crown procedure is accomplished in one visit.

Indications for Use:

For restoration of permanent teeth best restored with a single unit full crown (e.g. as an alternative to a complex multi-surface direct restoration)

Substantial Equivalence:

Information provided in this 510(k) submission shows that 3M™ ESPE™ Adult Crown is substantially equivalent to the predicate devices in terms indications for use and technology, including product formulation. A biocompatibility assessment was developed for 3M™ ESPE™ Adult Crown using standard risk assessment techniques and consideration of FDA & internationally recognized guidelines. The conclusion of the assessment is that 3M ESPE Adult Crown is safe for its intended use.

This 510(k) submission includes data from bench testing to evaluate the performance of 3M™ ESPE™ Adult Crown compared to predicate devices Paradigm™ MZ100 Block for CEREC® and Sinfony™ Indirect Lab Composite. The properties evaluated include Compressive Strength, Flexural Strength, Flexural Modulus, Depth of cure, Surface Hardness (Barcol), Radiopacity, Water sorption, Water solubility, Diametral Tensile Strength and Sensitivity to Ambient Light. Also included in this submission are the results of an In Vitro Chewing Simulation study comparing 3M™ ESPE™ Adult Crown and Paradigm™ MZ100 Block for CEREC®.

Based on bench testing conducted, the clinical performance of 3M™ ESPE™ Adult Crown is expected to be substantially equivalent to crowns produced using Paradigm™ MZ100 Block for CEREC® and Sinfony™ Indirect Lab Composite.



FEB 15 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K072733
Trade/Device Name: 3M™ ESPE™ Adult Crown
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: January 16, 2008
Received: January 18, 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.

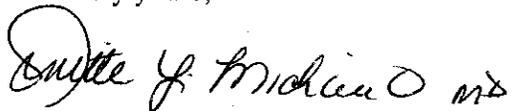
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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

3M ESPE

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K07 2733

Device Name: 3M™ ESPE™ Adult Crown

Indications for Use:

For restoration of permanent teeth best restored with a single unit full crown (e.g. as an alternative to a complex multi-surface direct restoration)

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)

Susan Kuonen

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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