

K062292

OCT 25 2006

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:	3M ESPE AG
Street:	ESPE Platz
ZIP-Code, City:	D-82229 Seefeld
Federal State:	Bavaria
Country:	Germany
Establishment Registration Number:	9611385
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Date:	August 02, 2006

Name of Device

Proprietary Name:	Unicem
Classification Name:	Dental cement other than zinc oxide-eugenol
Common Name:	Self adhesive cement

Predicate Device

Unicem by 3M ESPE, K 002364

Description for the Premarket Notification

Unicem is classified as a Dental cement other than zinc oxide-eugenol (21 C.F.R. §872.3275[b]) because it is a device composed of various materials other than zinc oxide-eugenol. Unicem is intended to affix dental devices such as crowns and bridges. Unicem currently is available in two single dose delivery systems called Unicem Aplicap™ and Unicem Maxicap™. The existing and 510(k) cleared device Unicem is modified as follows: A multi-dose handmix version of Unicem, called Unicem HM, will be added to the single dose delivery systems. Unicem HM is considered as a modification to its predicate device Unicem. Unicem HM consists of a base and catalyst base and will be available in 3M ESPE's multi-dose device Clicker™. The intended use of Unicem HM is the same as cleared for Unicem, and the slight differences in chemical composition have been assessed for any effects regarding biocompatibility. The physical and chemical properties of Unicem HM were compared to those of Unicem. Furthermore, the physical-chemical property to release fluoride ions is added to the product description of Unicem. For this purpose, the fluoride release rates of Unicem have been measured following the guidance document: "Dental Cements - Premarket Notification" issued by CDRH on August 18, 1998, section 6.0. In summary, Unicem modified as described in this 510(k) premarket notification submission is, in our opinion, substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Sabine Krischer
Regulatory Affairs Specialist
3M ESPE Dental Products
ESPE Platz
Seefeld, Bavaria
Germany D-82229

OCT 25 2006

Re: K062292
Trade/Device Name: Unicem
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: August 3, 2006
Received: August 7, 2006

Dear Dr. Krischer:

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.

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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

Indication for use: Adhesive fixing of ceramic, composite or metal inlays, onlays, crowns, bridges, posts, screws, veneers and orthodontic strips.

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STATEMENT OF INDICATIONS FOR USE

Device Name: Unicem

Indications for use: Adhesive fixing of ceramic, composite or metal inlays, onlays, crowns, bridges, posts, screws, veneers and orthodontic strips.

[The official form "Indications for Use" is to be found in the Administrative Part of this application]

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

510(k) Number: K062292