SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Dr Jan G Stannard
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DEVICE
Trade Name *CERCOM Cement*
Classification Name Cement, Dental
FDA Product Code 872 3275

JAN 2 6 2009

PREDICATE DEVICES
RelyX Cement, ESPE/3M
Variolink Cement, Ivoclar
Calibra Cement, Dentsply
Nexus Cement, Kerr

DESCRIPTION AND INTENDED USE

CERCOM Cement is a self-adhesive cement recommended for the bonding of ceramic and composite restorations

COMPARISON WITH PREDICATE PRODUCTS

CERCOM Cement is substantially equivalent in design, composition and intended use to the products listed above

SAFETY AND EFFECTIVENESS

CERCOM Cement is substantially equivalent in design, composition, performance, intended use and effectiveness to the predicate cement products listed above

The predicate products have been found substantially equivalent under the 510(k) premarket notification process as Class II Dental Devices under CFR EMA 872 3275

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr Jan G Stannard
President
Denali R&D Corporation
134 Old Washington Street
Hanover, Massachusetts 02339-1629

JAN 2 6 2009

Re K083398
Trade/Device Name CERCOM Cement
Regulation Number 21 CFR 872 3275
Regulation Name Dental Cement
Regulatory Class II
Product Code EMA
Dated November 12, 2008
Received November 17, 2008

Dear Dr Stannard

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" (21CFR 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,

Anthony D. Watson for
Ginette Y Michaud, M D
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) Number K083398
(if known)

Device Name

CERCOM Cement

Indications for Use:

CERCOM Cement is a self-adhesive cement recommended for the bonding of ceramic and composite restorations

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K083398

Prescription Use ✓ *or* *Over-The-Counter Use*
(Per 21 CFR 801 109)