K040375

APR - 2 2004

510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872
(717) 845-7511 (voice)
~~(717) 849-4762 (fax)~~
www.dentsply.com

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: February 11, 2004

TRADE OR PROPRIETARY NAME: IDEAL® 1 ORTHODONTIC BAND CEMENT

CLASSIFICATION NAME: Bracket adhesive and tooth conditioner resin (872.3750)

PREDICATE DEVICES: Ideal® 1 Orthodontic Bracket Adhesive K033703

DEVICE DESCRIPTION: The IDEAL® 1 ORTHODONTIC BAND CEMENT is a light-cure two-part system: an orthodontic cement and a primer. A tooth conditioner is available if desired for the highest stress bonding cases.

The cement is packaged in syringes. No mixing is necessary. The primer is packaged in unit dose, self-dispensing capsules.

INTENDED USE: The IDEAL® 1 ORTHODONTIC BAND CEMENT is indicated for bonding of orthodontic bands to natural and artificial tooth surfaces.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in the IDEAL® 1 ORTHODONTIC BAND CEMENT have been used in legally marketed devices.

We believe that the prior use of the components of the IDEAL® 1 ORTHODONTIC BAND CEMENT in legally marketed devices, the performance data provided, and the similarity of the predicate to the new device support the safety and effectiveness of the IDEAL® 1 ORTHODONTIC BAND CEMENT for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2004

Dentsply International
Mr. P. Jeffery Lehn
Director of Corporate Compliance & Regulatory Affairs
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, Pennsylvania 17405-0872

Re: K040375
Trade/Device Name: IDEAL®1 Orthodontic Band Cement
Regulation Number: 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: February 11, 2004
Received: February 17, 2004

Dear Mr. Lehn:

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 (301) 594-56. 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/dsma/dsmamain.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

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K040375

Device Name: **IDEAL® 1 ORTHODONTIC BAND CEMENT**

Indications for Use:

Bonding of orthodontic bands to natural and artificial tooth surfaces

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sima Porat

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

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