K061427

510(k) SUMMARY

JUN 26 2006

NAME & ADDRESS: DENTSPLY International
World Headquarters
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CONTACT: Helen Lewis

DATE PREPARED: May 17, 2006

TRADE OR PROPRIETARY NAME: PRE-IMPRESSION CONDITIONING SOLUTION

CLASSIFICATION NAME: Impression material, 872.3660

PREDICATE DEVICES: Xeno® III Dental Adhesive, K023776
Nupro® Prophylaxis Paste, K983966
Pretreatment Solution, K940685
Aquasil Easy Mix Putty Impression Material, K973781

DEVICE DESCRIPTION:
The PRE-IMPRESSION CONDITIONING Solution is a product to be used in the impression-taking process. When applied to substrates such as sulcular tissue; tooth preparations; ceramic, composite, or metal core build-up material; or implant abutments or copings, it provides a uniform surface condition with reduced surface tension prior to the application of an elastomeric impression material. This standardized surface with reduced contact angle on all impressed substrates allows capture of fine preparation detail both supra and subgingivally.

INTENDED USE:
The PRE-IMPRESSION CONDITIONING SOLUTION is indicated as a preparation conditioning solution for uniform surface wetting prior to elastomeric impression procedures.

TECHNOLOGICAL CHARACTERISTICS:
All of the components found in PRE-IMPRESSION CONDITIONING SOLUTION have been used in legally marketed devices and are safe for dental use. We believe that the prior use of the components of PRE-IMPRESSION CONDITIONING SOLUTION in legally marketed devices and the data provided, support the safety and effectiveness of PRE-IMPRESSION CONDITIONING SOLUTION for the indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2006

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K061427
Trade/Device Name: Pre-Impression Conditioning Solution
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Codes: ELW and MVL
Dated: May 17, 2006
Received: May 23, 2006

Dear Ms. Lewis:

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" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
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): K061427

Device Name: PRE-IMPRESSION CONDITIONING SOLUTION

Indications for Use:

Preparation conditioning solution for uniform surface wetting prior to elastomeric impression procedures

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

Susan Runner

...of Anesthesiology, General Hospital,
...on Control, Dental Devices

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