MAY 1 3 2002

510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

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K021416

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

CONTACT: P. Jeffery Lehn

DATE PREPARED: May 2, 2002

TRADE NAME: AQUASIL ULTRA MONOPHASE SMART WETTING IMPRESSION MATERIAL
AQUASIL ULTRA HEAVY SMART WETTING IMPRESSION MATERIAL
AQUASIL ULTRA LV SMART WETTING IMPRESSION MATERIAL

CLASSIFICATION NAME: Impression Material (872.3660)

PREDICATE DEVICE: Aquasil Monophase & Heavy and LV™ S.W. Impression Materials K946574

DEVICE DESCRIPTION: AQUASIL ULTRA MONOPHASE, AQUASIL ULTRA HEAVY, AND AQUASIL ULTRA LV SMART WETTING IMPRESSION MATERIALS are two-part catalyst/base hydrophilic vinylpolysiloxane impression materials used to record details of hard and soft tissues of the oral cavity. They are formulated for regular set and fast set. AQUASIL ULTRA MONOPHASE and AQUASIL ULTRA HEAVY SMART WETTING IMPRESSION MATERIALS are medium viscosity and available in (1:1 ratio) cartridges or (5:1 ratio) for bulk delivery. AQUASIL ULTRA LV SMART WETTING IMPRESSION MATERIAL is a light viscosity and is available in (1:1 ratio) cartridges.

INTENDED USE: AQUASIL ULTRA MONOPHASE, AQUASIL ULTRA HEAVY, AND AQUASIL ULTRA LV SMART WETTING IMPRESSION MATERIALS are used as impression materials in a dual phase impression technique. They may also be used for precise duplication of models. Use Regular Set for capturing multiple unit impressions. It is suitable for all impression techniques where the operator needs a monophase, heavy, or low viscosity material. Use Fast Set for capturing one preparation only (single unit crown); ideal for double arch dual phase techniques.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2002

Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Dentsply International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405

Re: K021416
Trade/Device Names: Aquasil Ultra Monophase Smart Wetting Impression Material Aquasil Ultra Heavy Smart Wetting Impression Material Aquasil Ultra LV Smart Wetting Impression Material
Regulation Number: 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: May 02, 2002
Received: May 03, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital 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): K021416

Device Names:
AQUASIL ULTRA MONOPHASE SMART WETTING IMPRESSION MATERIAL
AQUASIL ULTRA HEAVY SMART WETTING IMPRESSION MATERIAL
AQUASIL ULTRA LV SMART WETTING IMPRESSION MATERIAL

Indications for Use:

Used as impression materials in a dual phase impression technique. They may also be used for precise duplication of models. Use Regular Set for capturing multiple unit impressions. It is suitable for all impression techniques where the operator needs a monophase, heavy, or low viscosity material. Use Fast Set for capturing one preparation only (single unit crown); ideal for double arch dual phase techniques.

These are the same Indications for Use as previously cleared for the marketed devices (K943574).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021416