



NAME & ADDRESS:

DENTSPLY International
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(717) 845-7511
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K973781

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

CONTACT: P. Jeffery Lehn

DATE PREPARED: September 19, 1997

TRADE NAME: AQUASIL™ EASY MIX PUTTY IMPRESSION MATERIAL

CLASSIFICATION NAME: Impression Material

PREDICATE DEVICE:	Reposil® Putty Impression Material	K781151A
	Aquasil Smart Wetting® Impression Material	K943574

DEVICE DESCRIPTION: AQUASIL EASY MIX PUTTY IMPRESSION MATERIAL is a very high viscosity, elastomeric impression material with excellent hydrophilic properties, dimensional accuracy, high tear strength, and resistance to permanent deformation. AQUASIL EASY MIX PUTTY IMPRESSION MATERIAL consists of two-components (base paste and catalyst paste) which harden to form a base for final impressions. AQUASIL EASY MIX PUTTY IMPRESSION MATERIAL with "smart wetting" improves both wetting on the tooth surface and model detail reproduction. AQUASIL EASY MIX PUTTY IMPRESSION MATERIAL is designed to be used with Aquasil Regular Set Impression Materials.

INTENDED USE: AQUASIL EASY MIX PUTTY IMPRESSION MATERIAL is used as a tray material in a dual phase impression Technique. It is designed for taking multiple unit impressions of teeth and/or oral tissue.

TECHNOLOGICAL CHARACTERISTICS: All of the components of AQUASIL EASY MIX PUTTY IMPRESSION MATERIAL have been used in DENTSPLY legally marketed predicate devices or found to be safe for dental use.

Due to the similarity of the formulation of AQUASIL™ EASY MIX PUTTY IMPRESSION MATERIAL to the Aquasil Smart Wetting Impression Material, we believe that additional biocompatibility testing of the new impression material is unnecessary.

Aquasil Smart Wetting Impression Material was evaluated and the reports can be found in K943574:

The catalyst and base pastes and the mixed product were evaluated for cytotoxicity. The mixed product was evaluated for dermal toxicity, for irritation, and for mutagenicity.

The base pastes give a moderate cytotoxicity and the catalyst pastes were non-cytotoxic. When mixed, the cytotoxicity persisted, but was recorded as a lower value than the value for Reposil® Impression Material.

TRADE NAME: AQUASIL™ EASY MIX PUTTY IMPRESSION MATERIAL

The mixed product was tested by the Ames Mutagenicity Test, Acute Dermal Toxicity Test, and the Hamster Cheek Pouch Irritation Study. The final product is non-mutagenic, non-toxic, and a non-irritant.

As an impression material, AQUASIL EASY MIX PUTTY IMPRESSION MATERIAL is in the mouth for less than ten minutes.

We believe that the prior use of the components in legally marketed, the similarity of formulation to the predicate devices, the results of the final product testing of the predicate device, the limited exposure time in the mouth, and the performance data outlined above support the safety and effectiveness of AQUASIL EASY MIX PUTTY IMPRESSION MATERIAL for the intended uses.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. P. Jeffrey Lehn
Associate Director
Corporate Compliance
DENTSPLY International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17404

DEC 11 1997

Re: K973781
Trade Name: Aquasil™ Easy Mix Putty Impression Material
Regulatory Class: II
Product Code: ELW
Dated: September 19, 1997
Received: October 3, 1997

Dear Mr. Lehn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

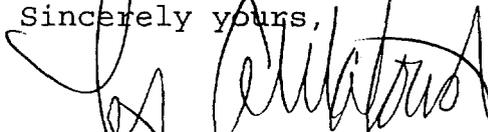
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(K) Number: _____

Device Name: AQUASIL™ EASY MIX PUTTY IMPRESSION MATERIAL

Indications for Use:

AQUASIL EASY MIX PUTTY IMPRESSION MATERIAL is used as a tray material in a dual phase impression Technique. It is designed for taking multiple unit impressions of teeth and/or oral tissue.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR

Over-The-Counter Use _____

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

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