

DENTSPLY

K973782

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CONTACT: P. Jeffery Lehn

DATE PREPARED: October 2, 1997

TRADE NAME: AQUASIL™ XLV SMART WETTING® IMPRESSION MATERIAL

CLASSIFICATION NAME: Impression Material

PREDICATE DEVICE: Aquasil™ Smart Wetting Impression Material K943574

DEVICE DESCRIPTION: AQUASIL™ XLV SMART WETTING IMPRESSION MATERIAL is an extra low viscosity, elastomeric impression material with excellent hydrophilic properties, dimensional accuracy, high tear strength, and resistance to permanent deformation. AQUASIL XLV IMPRESSION MATERIAL with "smart wetting" improves wetting both the tooth surface and the model detail reproduction.

AQUASIL XLV SMART WETTING IMPRESSION MATERIAL is available in Regular Set and Fast Set. It is available in cartridge delivery. In developing the Regular Set and Fast Set, adjustments were made to the active ingredients as compared to the predicate device (K943574). These adjustments were made to obtain two speeds of the material with improved physical properties. The speed of the materials was adjusted by increasing the amounts of catalyst and retarder fluids over the predicate device. These changes improved the setting properties of the mixed impression material and allowed for two speeds of the same viscosity of impression material. Other changes were made to improve the flow property of the mixed impression material and the shelf stability of the product.

INTENDED USE: AQUASIL™ XLV SMART WETTING IMPRESSION MATERIAL is a two-part (base/catalyst) hydrophilic vinylpolysiloxane (VPS), impression material used to record the details of hard and soft surfaces of the oral cavity.

Aquasil™ XLV Smart Wetting Impression Material is used as an impression material in a dual phase impression technique. It may also be used for precise duplication of models.

Regular Set is used for capturing multiple unit impressions. It is suitable for all impression techniques where the operator needs an extra low viscosity material.

Fast Set is used for capturing one preparation only (single unit crown); ideal for double arch dual phase techniques.

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TRADE NAME: AQUASIL™ XLV SMART WETTING® IMPRESSION MATERIAL

TECHNOLOGICAL CHARACTERISTICS: All of the components of AQUASIL XLV SMART WETTING IMPRESSION MATERIAL have been used in DENTSPLY legally marketed devices.

Due to the similarity of the formulation of AQUASIL XLV SMART WETTING IMPRESSION MATERIAL to the predicate device (K943574), we believe that additional biocompatibility testing of the new impression material is unnecessary.

The predicate device, 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 Reprosil® 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 impression materials, AQUASIL XLV SMART WETTING IMPRESSION MATERIAL and the predicate device (K943574) are in the mouth for less than ten minutes.

We believe that the prior use of the components in DENTSPLY legally marketed devices, the similarity of formulation to the predicate device, 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 XLV SMART WETTING IMPRESSION MATERIAL for the intended uses.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 1997

Mr. P. Jeffrey Lehn
Director, Corporate Compliance and Regulatory Affairs
DENTSPLY International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K973782
Trade Name: Aquasil XLV Smart Wetting Impression
Material
Regulatory Class: II
Product Code: ELW
Dated: October 2, 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.

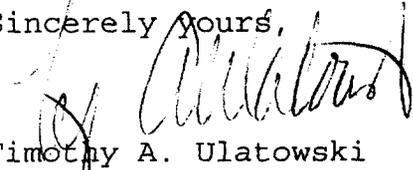
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

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) 594-4618. 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: K973782

Device Name: AQUASIL™ XLV SMART WETTING® IMPRESSION MATERIAL

Indications for Use:

Aquasil™ XLV Smart Wetting Impression Material is used as an impression material in a dual phase impression technique. It may also be used for precise duplication of models.

Regular Set is used for capturing multiple unit impressions. It is suitable for all impression techniques where the operator needs an extra low viscosity material.

Fast Set is used for capturing one preparation only (single unit crown); ideal for double arch dual phase techniques.

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 K973782

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