DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 4, 2016

DENTSPLY International, Inc.
Ms. Helen Lewis
Director, Corporate Regulatory Affairs
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Re: K152861
Trade/Device Name: Aquasil® Ultra+ Smart Wetting® Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: February 3, 2016
Received: February, 04, 2106

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 801and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K152861

Device Name: Aquasil® Ultra + Smart Wetting® Impression Material

Indications for Use:

Aquasil® Ultra + Smart Wetting® Impression Material is indicated for all dental impression techniques.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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SECTION 5. 510(k) SUMMARY

for
Aquasil® Ultra + Smart Wetting® Impression Material

1. Submitter Information**:**

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343

Date Prepared: 28 September 2015

2. Device Name:

- Proprietary Name: Aquasil® Ultra + Smart Wetting® Impression Material
- Classification Name: Impression Material
- CFR Number: 872.3660
- Device Class: II
- Product Code: ELW

3. Sponsor's Predicate Device:

- 510(k) cleared under K113406 - Aquasil® Ultra Smart Wetting® Impression Material

4. Description of Device:

Aquasil® Ultra+ Smart Wetting® Impression Material is a quadrafunctional hydrophilic addition reaction silicone elastomeric dental impression material with excellent hydrophilic properties, dimensional accuracy, high tear strength, and resistance to permanent deformation.

5. Indications for Use:

Aquasil® Ultra + Smart Wetting® Impression Material is indicated for all dental impression techniques.

6. Substantial Equivalence:

Technological Characteristics.

The Aquasil® Ultra + Smart Wetting® Impression Material represents a modification to the 510(k) cleared under K113406. The modification to the Aquasil® Ultra Smart Wetting® Impression Material XLV (Extra Low Viscosity) is removal of the current surfactant and replaced with a mixture of two other surfactants in the base paste. The modification to the Aquasil® Ultra Smart Wetting® Impression Material LV (Low Viscosity) is removal of the current surfactant and replaced with a mixture of two other surfactants in the base paste. This change allows for a faster wetting of water on the surface of the impression material.

Similarities and Differences between the proposed and the predicate devices

Proposed Device Aquasil® Ultra + Smart Wetting® Impression Material	**Predicate Device** Aquasil Ultra® Smart Wetting® Impression Material K113406
Indications for Use: Aquasil® Ultra + Smart Wetting® Impression Material is indicated for all dental impression techniques.	**Indications for Use:** Aquasil® Ultra Smart Wetting® Impression Material is indicated for all dental impression techniques.
Surfactant-Fluoroaliphatic oxyethylene adduct	Surfactant-Polyoxyethylene modified polydimethylsiloxane
Contains: • silicone polymers and cross linker • organoplatinum complex catalyst • retarder • platinum calcium carbonate degassing concentrate • wetting agent • peppermint oil • fillers • pigments	Contains • silicone polymers and cross linker • organoplatinum complex catalyst • retarder • platinum calcium carbonate degassing concentrate • wetting agent • peppermint oil • fillers • pigments
Can be self-cured after mixing two separate parts	Can be self-cured after mixing two separate parts
Two parts are separated and mixed prior to use	Two parts are separated and mixed prior to use
Paste/paste systems in dual-barrel syringes and delivered through auto-mix tip	Paste/paste systems in dual-barrel syringes and delivered through auto-mix tip
High tear strength	High tear strength
Can be dispensed from cartridge dispensing gun	Can be dispensed from cartridge dispensing gun

7. Non-Clinical Performance Data

The performance of the Aquasil® Ultra + Smart Wetting® Impression Material satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence. The results of the biocompatibility testing of Aquasil® Ultra + Smart Wetting® Impression Material are equivalent to the predicate device Aquasil® Ultra Smart Wetting® Impression Material 510(k) cleared under K113406.

The table below displays the necessitated biocompatibility and performance testing from the change in the surfactant.

Physical Property	Results
Wettability (Contact Angle)	Meets Internal DENTSPLY procedure requirements
Mechanical (Compressive Strength, Tear Strength)	Meets Internal DENTSPLY procedure requirements
Uncured Base Paste – Cytotoxicity Study Using the ISO Elution Method – (Test article incubated for 10 minutes.)	Meets ISO Elution Method requirements
Uncured Catalyst Paste – Cytotoxicity Study Using the ISO Elution Method	Meets ISO Elution Method requirements
Cured Base/Catalyst – Cytotoxicity Study Using the ISO Agarose Overlay Method	Meets ISO Agarose Overlay Method requirements
ISO Oral Mucosal Irritation Study in Hamsters - Collar Method – 24 Hrs.	Meets ISO Oral Mucosal Irritation requirements
ISO Guinea Pig Maximization Sensitization Test	Meets ISO Guinea Pig Maximization Sensitization Test requirements
OECD 425 Acute Oral Toxicity Study in Rats, Limit Test	Meets OECD 425 Acute Oral Toxicity requirements

Biocompatibility Conclusion:
The test results of Aquasil Ultra + Smart Wetting® Impression Material LV Base and Catalyst paste, met the requirements of the three recommended biocompatibility tests; as per ISO10993-1:2009; Cytotoxicity, Sensitization (Delayed-type hypersensitivity), and Irritation or intracutaneous reactivity. These results were equivalent to the results from the same tests of Aquasil® Ultra Smart Wetting® Impression Material included in 510(k) cleared under K113406.

Risk Analysis Activities:
A Risk Management system is employed as part of the Design Control process. This includes, but is not limited to, the development of a Design Failure Modes and Effects Analysis (dFMEA) to evaluate any risks associated with the design of the product. Additionally, a Process FMEA (pFMEA) is developed to specifically address the manufacturing process. The individual risks are evaluated and mitigated, as needed. This may include additional Verification and Validation activities in order to demonstrate that the Design Outputs meet the Design Input requirements. At the conclusion of all Risk Management activities, residual risk for the product is determined.

Design Control Procedures:
The Design Control procedures that are used at DENTSPLY comply with all requirements outlined in 21 CFR §820.30. These procedures represent an effective Design Control process that addresses Design and Development Planning, Design Inputs, Outputs, Reviews, Verification, Validation, Transfer, and Changes. All of the documents that are generated over the course of the development effort result in the assembly of the Design History File.

Verification & Validation Activities:
All required verification and validation activities, as identified through risk analysis were performed by designated individuals and the results indicate that the design meets all predetermined acceptance criteria. Furthermore, the manufacturing facility is in conformance with the design control procedures requirements outlined in 21 CFR §820.30. The records addressing this compliance are available for review.

8. Conclusion Regarding Substantial Equivalence

The Aquasil® Ultra + Smart Wetting® Impression Material is an Elastomeric Impression Material which is intended to reproduce the hard and soft tissue in the mouth. The Aquasil® Ultra + Smart Wetting® Impression Material has the same intended use, incorporates the same fundamental technology, and has the same indications for use as the predicate Aquasil® Ultra Smart Wetting® Impression Material cleared under premarket notification K113406.

Design control activities have been conducted to verify that the Aquasil® Ultra + Smart Wetting® Impression Material meets the design requirements and intended use. The Aquasil® Ultra + Smart Wetting® Impression Material meets the requirements of ISO 4823 Dentistry – Elastomeric Impression Materials. Other tests, including Contact Angle and Tear Strength were performed and the results of these activities, combined with the design and intended use comparison with the predicate device, support substantial equivalence.