September 9, 2022

Prevest Denpro Limited
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K213244
Trade/Device Name: Accusil Dental Impression Materials (Accusil Light Body Regular and Fast Set, Accusil Heavy Body Regular and Fast Set, Accusil Monophase Regular and Fast Set, Accusil Putty Regular and Fast Set, Accusil Bite Registration)
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: September 29, 2021
Received: September 30, 2021

Dear Angela Blackwell:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213244

Device Name

Accusil Dental Impression Material: Accusil Light Body Regular and Fast Set, Accusil Heavy Body Regular and Fast Set, Accusil Monophase Regular and Fast Set, Accusil Putty Regular and Fast Set, Accusil Bite Registration

Indications for Use *(Describe)*

Accusil Dental Impression Material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K213244

Accusil Dental Impression Materials (Accusil Light Body Regular and Fast Set, Accusil Heavy Body Regular and Fast Set, Accusil Monophase Regular and Fast Set, Accusil Putty Regular and Fast Set, Accusil Bite Registration)

510K Summary

April 29, 2022

Name and Address: PrevestDenpro Limited
Export Promotion Industrial Park
Bari Brahmana, Jammu 181133 India
Contact Person: Atul Modi
Email:prevestindia@gmail.com
Telephone: (941) 919 4280

Name of device: Accusil Dental Impression Materials (Accusil Light Body Regular and Fast Set, Accusil Heavy Body Regular and Fast Set, Accusil Monophase Regular and Fast Set, Accusil Putty Regular and Fast Set, Accusil Bite Registration)

Common name: impression material
Classification Name: impression material
CFR: 21 CFR 872.3660
Primary Product Code:ELW

Submission Contact:

Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
(704)450-9934
angela@blackwelldevice.com

Device Description:

Accusil Dental Impression Materials are designed for dental applications to define and reproduce the structure of a patient's teeth and gums for producing crowns, bridges, occlusal models and dental implant restorative devices. Base and catalyst components are mixed in an equal ratio 1:1, placed into an impression tray and inserted into the patient's mouth. The material will conform to the patient's dentition and when set will produce a reproduction of the patient's teeth and occlusion.

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Indications for Use:

Accusil Dental Impression Material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums.

Testing Summary:

Accusil light, heavy, monophase and putty were tested with protocols meeting ISO 4823 and ISO 48-4 for working time, detail reproduction, linear dimensional change, consistency, Shore hardness, compatibility with gypsum, elastic recovery, and strain in compression. Setting time was tested using internal protocols (ISO 4823 does not have setting time). Accusil bite registration was tested with protocols meeting ISO 4823 and ISO 48-4 for working time, linear dimensional change, Shore hardness and compression and tested using an internal protocol for setting time.

Shelf life testing was completed on all devices using relevant protocols also used for the physical characteristics tested. Shelf life for impression materials is 3 years.

All tests results met the criteria in standards.

The impression materials contain ingredients found in the predicate and reference devices. They are used for the same type of contact, external communicating with contact to tissue/bone/dentin. The indications for use of the devices and the predicate devices are the same so the risks incurred for use of the ingredients are the same. Since no new risks are introduced, no biocompatibility testing was done.

Predicate Device: Dynax Dental Impression Material K171562

Reference Devices: Fresh Impression Material K053427, President the Original, K220097, Aquasil Ultra + K152861

Substantial Equivalence:

The impression materials have similar ingredients to the predicate and reference devices, the same indications for use, and similar physical parameter testing.

Accusil Dental Impression Materials

Name	Accusil (light body, heavy body, monophase, putty and bite registration)	Dynax (clear, putty, heavy body, light, mono) predicate device	Fresh Impression Material (reference device for ingredients)	President the Original (reference device for ingredients)	Aquasil Ultra + (reference device for ingredients)
510k Number	K213244	K171562	K053427	K220097	K152861
Common Name	Impression material	Impression material	Impression material	Impression material	Impression material
Classification Name	Impression material	Impression material	Impression material	Impression material	Impression material
Class	II	II	II	II	II

Product Code	ELW	ELW	ELW	ELW	ELW
CFR	872.3660	872.3660	872.3660	872.3660	872.3660
Indications for Use	Accusil dental impression material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums.	Dynax dental impression material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums.	Fresh Dental Impression material is intended for use with all crowns, bridges, occlusal and dental implant impression techniques to reproduce the structure of a patient's teeth and gums.	PRESIDENT The Original Xtra light body **/** light body **/** regular body: * Correction material for the corrective impression technique * Injection material for the double mix technique * Injection material for the dual arch technique)) * Lining impression material **PRESIDENT** The Original heavy body: * Impression material for pick-up impression in the double mix technique * Tray material for corrective impression technique * Tray material for dual arch technique **PRESIDENT** The Original System **360:** * Impression material for pick-up impression in	Aquasil® Ultra + Smart Wetting® Impression Material is indicated for all dental impression techniques.

				the double mix technique * Tray material for corrective impression technique * Tray material for dual arch technique **PRESIDENT** The Original putty **/** putty soft **/** putty super soft **/** fast putty soft * Impression material for pick-up impression in the double mix technique * Tray material for corrective impression technique	
Material	Accusil light, heavy, mono, and bite registration: Mixture of vinyl terminated polydimethylsiloxanes and filler materials with platinum catalyst and SIH capped polysiloxane Accusil putty: Mixture of vinyl terminated polydimethylsiloxanes and filler materials with	Dynax putty, light, mono, and heavy body: Mixture of vinyl terminated polydimethylsiloxanes and filler materials with platinum catalyst and methylhydrosiloxane dimethylsiloxane copolymers Dynax clear: Mixture of vinyl terminated	Fresh Bold liquid putty, light body, monophase and heavy body: Mixture of vinyl terminated polydimethylsiloxanes and filler materials with platinum catalyst and methylhydrosiloxane dimethylsiloxane copolymers Fresh Bold clear bite:	Divinylpolydimethylsiloxanes, silicon dioxide, zeolite, Platinum(0)-1,3-divinyl-1,1,3,3-tetramethyldisiloxane complex solution, Titanium dioxide, iron oxides, organic pigments, and surfactants	Polydimethyl siloxane polymer, polymethylhydrogen siloxane, silicon dioxide, sodium aluminosiliicate (zeolite), organic platinum complex, titanium dioxide, iron oxide pigments, organic pigments, other pigments. Surfactants, peppermint oil

	platinum catalyst and SIH capped polysiloxane plus softener	polydi-methylsiloxanes and silicic acid with platinum catalyst and methylhydrosiloxane dimethylsiloxane copolymers	Mixture of vinyl terminated polydimethylsiloxanes and silic acid with platinum catalyst and methylhydrosiloxane dimethylsiloxane copolymers		
Working/Processing Time	40-150 sec	90 sec	90-120 sec	unknown	35-105 sec
Setting time/Time in the mouth	60-300 sec	90 sec	120-140 sec	unknown	150-330 sec
Hardness	63-70 Shore A	46-70 Shore A	42-70 Shore A	50-75 Shore A	Unknown
Working humidity	50%	50%	50%	unknown	Unknown
Dimensional accuracy	99.9%-99.2%	99.9%-99.2%	99.9% - 99.2%	99.8%-99.2%	98%
Stability (linear dimensional change)	<0.8% typical	<0.2% typical	<0.1% typical	unknown	<0.50% typical
Consistency	Type 0-type 3 ISO 4823	Type 0-type 3 ISO 4823	Type 0-type 3 ISO 4823	Type 1-type 3 ISO 4823	Type 1-type 3 ISO 4823
Chemical Description	Room temperature vulcanizing 2-components silicone	Room temperature vulcanizing 2-components silicone	Room temperature vulcanizing 2-components silicone	Room temperature vulcanizing 2-components silicone	Room temperature vulcanizing 2-components silicone
Package	Accusil bite registration, heavy, light, and monophase come in 2 x 50 ml double cartridges Monophase regular also comes in a 5:1 380ml double cartridges. Accusil putty comes in plastic jars of 150ml and 300ml for both base and catalyst.	Dynax putty in tubs of 2x35 ml and 2 x 450 ml Dynax light, mono, heavy body, and clear are sold in 50 ml double cartidges	Fresh Bold liquid putty in tubs of 2 x 450 ml Fresh Bold light body, monophase, heavy body and clear bite in 2x 50 ml double cartridges	Primary packaging Tubes, Pots or cartridges Secondary packaging: Folding carton	Primary packaging Tubes, Pots or cartridges Secondary packaging: Folding carton

Method of manipulation	Preformed impression tray	Preformed impression tray	Preformed impression tray	Preformed impression tray	Preformed impression tray
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile

Conclusion: Accusil dental impression materials are substantially equivalent to the predicate device, Dynax dental impression materials. They have the same indications, similar testing, and very similar ingredients. References devices contain ingredients not found in the predicate device but found in Accusil. Setting time, working time, hardness, working humidity, and stability are similar to the predicate device and/or reference devices. The testing for these parameters for the subject device, predicate device, and reference devices are according to ISO 4823 so there are no differences in test methods. Since the test results are in the same ranges and the test methods are according to the same standard these results support the substantial equivalence of Accusil to Dynax. The subject devices, predicate devices, and reference devices all have the same method of manipulation, same working humidity, and same ISO 4823 types. Both the subject devices and the predicate device have physical parameters which meet requirements of the relevant ISO standards. Any differences in ingredients are minor and do not change the substantial equivalence.