January 13, 2022

Coltène/Whaledent AG
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K220097
Trade/Device Name: PRESIDENT The Original
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression material
Regulatory Class: Class II
Product Code: ELW
Dated: January 7, 2022
Received: January 12, 2022

Dear Dave Yungvirt:

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)*

K220097

Device Name
PRESIDENT The Original

Indications for Use *(Describe)*

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 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

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.

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K220097

510(k) Summary

5.1 Submitter

Company Name:	Coltène/Whaledent AG
Street and Nr.:	Feldwiesenstrasse 20
City:	Altstätten
Post Code:	9450
State/Canton:	St. Gallen
Country:	Switzerland

5.2 Submitter contact:

Regulatory contact:	Akanksha Nagpal Regulatory
Title:	Affairs Manager
Phone:	+ 41 71 757 5385
Email:	akanksha.nagpal@coltene.com

5.3 Date prepared

31st March 2021

5.4 Device identification

Trade Name:	PRESIDENT® The Original
Common Name:	addition type silicone-based impression materials for use in dentistry
Classification Name:	Impression material
Regulation Number:	21 CFR 872.3660
Product Code:	ELW
Class:	II
Classification Panel:	Dental

5.5 Device overview

The subject device family is PRESIDENT The Original. PRESIDENT The Original (**Figure 1**) which consists of addition type silicone based dental impression materials. PRESIDENT The Original is the relaunch and improved version of the predecessor device PRESIDENT (K811767), which is on the market since 1981.

PRESIDENT The Original is a two base system consisting of base and catalyst that are mixed together before use. The product portfolio of the subject device PRESIDENT The Original can be broadly subdivided into tray materials and wash materials, according to their physical and chemical properties.

The tray materials have a higher tear strength and elasticity than the wash materials. PRESIDENT The Original System 360 devices are surface activated and thixotropic with fast pressure build up so that the wash material is driven into the clinically critical areas. PRESIDENT The Original putties are offered in three different end hardness` for each individual case.

PRESIDENT The Original wash materials are stable but also free-flowing under pressure to capture all details precisely. The hydrophilic properties are effected by surfactants in the material. In contact with moisture these additives move to the surface and decrease the surface tension, resulting in an improved wettability. Furthermore, new colors were added to provide a better contrast between wash and tray materials and to allow a more accurate detail readability.

Figure 1: Device family overview of the subject device PRESIDENT The Original.

5.6 Indication for use

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 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

5.7 Primary predicate device Aquasil® Ultra+ (K152861) by Dentsply Sirona

The primary predicate device chosen is Aquasil® Ultra+ by Dentsply Sirona. Aquasil® Ultra+ was cleared in March 2016 under the 510(k) number K152861 (Exhibit 5-1). *Aquasil® Ultra+ putty regular* and *Aquasil® Ultra+ medium regular* were chosen to claim substantial equivalence with the new device PRESIDENT® The Original. *Aquasil® Ultra+ medium regular* was chosen as the predicate device for PRESIDENT The Original Xtra light body, light body, regular body, (System 360) MonoBody, (System 360) heavy body, heavy body and *Aquasil® Ultra+ putty regular* was chosen as the predicate device for PRESDIENT the Original putty, putty soft, putty super soft and fast putty soft.

5.8 PRESIDENT The Original chemical composition

PRESIDENT The Original family devices are addition type sillicone-based dental impression materials composed of polyvinylsiloxanes, addition type/surface activated silicone elastomers in various compositions to achieve different viscosities and flow properties depending on the intended use.
To start the curing process the base material needs to be mixed with the corresponding catalyst material. The setting occurs via an addition reaction. The base materials consist of polyvinylsiloxanes, inorganic silicon fillers and other additives (e.g. coloring pigments). In all PRESIDENT The Original family members, except the putty consistencies, surfactants are used to increase hydrophilicity of the impression material. An overview of the chemical composition of PRESIDENT The Original and Aquasil® Ultra+ is shown in **Table 1**.

Table 1: Chemical composition of PRESIDENT The Original compared to the predicate device Aquasil® Ultra+. A detailed chemical composition for the subject device is provided in Section 11 – Device Description).

Chemical Compound Group	Subject Device: PRESIDENT The Original	Predicate Device: Aquasil® Ultra+ medium regular	Predicate Device: Aquasil® Ultra+ putty regular
Organopolysiloxanes	Divinylpolydimethylsiloxanes	Polydimethyle siloxane polymer	Polyvinyl siloxane
		Polymethylhydrogen siloxane	Methylhydrogene siloxane
Inorganic filler	Silicon dioxide	Silicon dioxide	Silicon dioxide
	Zeolite	Sodium Aluminosilicate (Zeolite)	-
Organic platinum catalyst	Platinum(0)-1,3-divinyl-1,1,3,3-tetramethyldisiloxane complex solution	Organic Platinum Complex	Organic Platinum Complex
Surfactants	Surfactant (except in putties)	Surfactant	-
Pigments	Titanium Dioxide	Titanium Dioxide	Pigments
		Fluorescent Pigments	
		Metallic Oxide Pigments	
	Iron Oxide Pigments	Iron Oxide Pigments	
	Organic Pigments	Organic Pigments	
Flavour	-	Peppermint Oil	-

PRESIDENT The Original and Aquasil® Ultra+ devices are classified as surface-contacting medical devices according to ISO 10993-1:2018 Section 5.2.2 and have a short-term contact (<24 h) with tissue and dentin.

5.9 Substantial Equivalence Discussion

A comparison of the subject device PRESIDENT The Original and the primary predicate device Aquasil® Ultra+, with respect to their physical state, structure, materials, mechanical properties, indications for use, packaging, biocompatibility and performance testing, is shown in **Table 2**.

Table 2: Comparison of device characteristics of the subject device PRESIDENT The Original and the predicate device Aquasil® Ultra+.

Attributes	Predicate Device *Aquasil® Ultra+ medium regular*	Predicate Device *Aquasil® Ultra+ putty regular*	Subject Device PRESIDENT The Original	Similarities / Differences
Device Name	Aquasil® Ultra+ medium regular	Aquasil® Ultra+ putty regular	PRESIDENT The Original	-
Manufacturer	Dentsply Caulk, Milford DE, USA	Dentsply Caulk, Milford DE, USA	Coltène/Whaledent AG, Switzerland	-
510(k) Number	K152861	K152861	Pending	-

Attributes	**Predicate Device** *Aquasil® Ultra+ medium regular*	**Predicate Device** *Aquasil® Ultra+ putty regular*	**Subject Device** PRESIDENT The Original	**Similarities / Differences**
Product Code	ELW	ELW	ELW	
Regulation	872.3660	872.3660	872.3660	Same
Class	II	II	II	Same
Review Panel	Dental	Dental	Dental	Same
Device Image			  PRESIDENT The Original Xtra light body, light body, regular body  PRESIDENT The Original MonoBody / heavy body	-
			 PRESIDENT The Original Putties	
Indications for Use	Aquasil® Ultra+ Material is indicated for all dental impression techniques.	Aquasil® Ultra+ Putty materials are thick, vinyl polysiloxane dental impression materials intended to be used in conjunction with more fluid vinyl polysiloxane impression materials in order to make impressions. The resulting impressions are used to make plaster models of the teeth.	**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 **heavy body:** • Impression material for pick-up impression	The subject and predicate device have the same intended use. Both devices are used for dental impression techniques according to their consistencies.

Attributes	**Predicate Device** *Aquasil® Ultra+ medium regular*	**Predicate Device** *Aquasil® Ultra+ putty regular*	**Subject Device** PRESIDENT The Original	**Similarities / Differences**
			in the double mix technique • Tray material for corrective impression technique • Tray material for dual arch technique **System 360:** • Impression material for pick-up impression in the double mix technique • Tray material for corrective impression technique • Tray material for dual arch technique	
			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	
Physical State	Viscous pastes with various viscosity and putties with various elasticities	Viscous pastes with various viscosity and putties with various elasticities	Viscous pastes with various viscosity and putties with various elasticities	The subject and predicate devices are provided as viscous pastes with various viscosities and putties with various elasticities. The physical states are similar.
Structure	Addition type silicone based elastomeric impression materials	Addition type silicone based elastomeric impression materials	Addition type silicone based elastomeric impression materials	The subject and the predicate device are supplied as pastes and putties. The new device and its predecessor differ slightly in composition, physical properties and color.
Packaging	Primary packaging Tubes, Pots or cartridges Secondary packaging:	Primary packaging: Tubes, Pots or cartridges Secondary packaging:	Primary packaging: Tubes, Pots or cartridges Secondary packaging:	The subject and predicate device are packaged the same way according to their physical state.

Attributes	Predicate Device *Aquasil® Ultra+ medium regular*	Predicate Device *Aquasil® Ultra+ putty regular*	Subject Device PRESIDENT The Original	Similarities / Differences
	Folding carton	Folding carton	Folding carton	
Usage	Single patient, single use. Not reusable	Single patient, single use. Not reusable	Single patient, single use. Not reusable	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Handling System	Two part base/catalyst system	Two part base/catalyst system	Two part base/catalyst system	Same
Type of Curing	Self-curing after mixing of base and catalyst part.	Self-curing after mixing of base and catalyst part.	Self-curing after mixing of base and catalyst part.	Same
Biocompatibility	Conforms with ISO 10993-1	Conforms with ISO 10993-1	Conforms with ISO 10993-1	Same
Performance	Conforms with ISO 4823	Conforms with ISO 4823	Conforms with ISO 4823	Same

5.10 Non-Clinical Performance Data

As part of demonstrating substantial equivalence of PRESIDENT The Original to the predicate device Aquasil® Ultra+ (K152861), Coltène/Whaledent AG has performed extensive testing of the finished device in accordance with the applicable parts of the following voluntary standards, or according to the company's own internal test protocols.

- ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
- ISO 4823:2021: Dentistry -- Elastomeric impression materials
- ISO 15223-1:2016 Medical devices – Symbols to be used with medical devices labels, labeling, and information to be supplied – Part 1: General requirements.
- ISO 7405:2018 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- ISO/TR 10993-22:2017 Biological evaluation of medical devices – Part 22: Guidance on nanomaterials
- FDA General Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", September 4, 2020.
- ISO 14971:2019 Medical devices - Application of risk management to medical devices
- ISO 82079-1:2012: Preparation of information for use (instructions for use) of products - Part 1: Principles and general requirements
- IEC 62366-1:2015: Medical devices - Part 1: Application of usability engineering to medical devices

- IEC/TR 62366-2:2016: Medical devices – Part 2: Guidance on the application of usability engineering to medical devices

The device testing evaluated mixing time, consistency, working time, detail reproduction, , linear dimensional change, elastic recovery, strain in compression, and compatibility with gypsum according to ISO 4823:2021. Also an extensive biocompatibility testing according to ISO 10993-1 was conducted.

5.11 Statement of Substantial Equivalence

PRESIDENT The Original has the same intended use, indications for use and similar chemical and physical attributes as the predicate device Aquasil® Ultra+ (K152861) (with consistencies ranging from putties to light body consistencies). Any minor differences in the used materials and compositions to make the subject device, when compared to the predicate device have been successfully evaluated by Coltène/Whaledent AG through performance and biocompatibility testing on the subject device. The information submitted to the FDA demonstrates that the subject device is as safe and as effective as the predicate device and does not raise any new questions or concerns regarding safety and effectiveness. In conclusion the subject device PRESIDENT The Original has been determined to be substantially equivalent to the predicate device Aquasil® Ultra+ (K152861).