



Food and Drug Administration
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August 5, 2016

Sybron Dental Specialties
Mr. Gerardo Lara
Regulatory Affairs Specialist
1717 W. Collins Ave
Orange, California 92867

Re: K160097

Trade/Device Name: Image Alginate Dental Impression Materials
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: June 24, 2016
Received: June 28, 2016

Dear Mr. Lara:

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 801); 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), 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,

 Tina
Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160097

Device Name

Image Alginate Dental Impression Materials

Indications for Use (Describe)

Image Alginate Dental Impression materials are irreversible hydrocolloids for dental impressions used by the dentist to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define the required interventions and/or check their effectiveness. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.

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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**510(k) SUMMARY
For Image Alginate
Dental Impression Materials
K160097**

1. Submitter Information:

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92867

Contact Person: Gerardo Lara
Telephone Number: 909-962-5771
Fax Number: 909-962-5694

Date Prepared: August 2, 2016

2. Device Name:

- Proprietary Name: Image Alginate Dental Impression Materials
- Common Name: Dental Impression Material
- Classification Name: Impression Material
- CFR Number: 872.3660
- Device Class: 2
- Product Code: ELW

3. Predicate Device:

The Image Alginate product lines are substantially equivalent to the legally marketed devices Identic Alginate and KromaFaze Alginate product lines cleared on June 30th, 2016 (K160441), product code ELW.

4. Description of Device:

Alginate impression materials are elastic, irreversible hydrocolloid impression materials made from seaweed. They are used to take primary or preliminary impressions of a patient's teeth and gums. This colloidal material forms a gel when the powder is mixed with water. It solidifies into an elastic mass capable of producing a negative reproduction of the oral cavity (an impression). Alginate impressions are taken to obtain diagnostic study models, which are the positive reproductions of the teeth and surrounding structures. They are also used to fabricate bleaching trays and mouth guards. Alginate is the most universally utilized impression material in dentistry. Image Alginate is a green-colored, mint flavored alginate and comes in two options Regular Set, Fast Set. The packaging configurations include a 1 lb. (454 g) bag and a singles pack of 18 g.

Accessories Used with Identic and KromaFaze	Manufacturer of Accessory
Impression Tray	DUX Dental 600 East Hueneme Road Oxnard, CA 93033 USA

5. Indications for Use:

Image Alginate Dental Impression Materials are irreversible hydrocolloids for dental impressions used by the dentist to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define the required interventions and/or check their effectiveness. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics

The designs of Image Alginate are very similar to the predicate Identic and KromaFaze Impression Material (K160441), as they are all alginates used as general dental and orthodontic impression materials. They are all considered class II impression materials compliant to ISO 1563:1990 for Dental Elastic Impression Materials Part 2 Alginate dental impression material. The differences between the proposed and predicate devices include the flavor. Image Alginate is mint flavored, KromaFaze is mint flavored with a color change feature, and Identic is cinnamon flavored. Identic is offered in an extra fast set configuration, while KromaFaze Alginate and Image Alginate are not.

Non-Clinical Performance Data

Non-clinical performance data included testing for Work time, Dimensional Changes, Set Time, Mixing Time, Biodegradable Components, Derivatives, Dust Prevention, Mixing Ratio, Warm/Hard Water Setting, Cold Water Setting, Towel Wrap Dimensional Changes, Full Setting, Singles Mixing Ratio, Color & Scent, Smooth Surface, Gypsum Compatibility, Compressive Strength, Powder Uniformity, Homogeneous Material, Penetration Value, Elastic Recovery, Strain in Compression, Gypsum Cast Material, Color Change for KromaFaze, as well as Biocompatibility and Stability testing.

Following the assessment route in ISO 10993-1:2009 Biological Evaluation of Medical Devices, Annex A, Biocompatibility testing was performed at a third party laboratory and testing results proved the proposed Image Alginate Alginate Impression material met the biocompatibility requirement.

The following standards were utilized for the non-clinical performance testing:

- Guidance for Industry and FDA Staff: Dental Impression Materials – Premarket Notification [510(k)] Submissions, August 17, 1998
- ISO 1563:1990 for Dental Elastic Impression Materials part 2 Alginate dental impression material

- ISO 10993-1: 2009 Biological Evaluation of Medical Devices
- ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests for in Vitro Cytotoxicity

Predicate and Proposed Device Comparison Table

Element	Predicate Identic Alginate (K160441)	Predicate KromaFaze Alginate (K160441)	Proposed Image Alginate (K160097)
510(k)	K160441	K160441	K160097
Trade Name	Identic Alginate	KromaFaze Alginate	Image Alginate
Target Users	Licensed dental professionals	Licensed dental professionals	Licensed dental professionals
Device Description	Identic is an elastic, irreversible hydrocolloid impression material.	KromaFaze Alginate is an elastic irreversible hydrocolloid impression material	Image Alginate is an elastic irreversible hydrocolloid impression material
Common Name	Alginate Impression Material	Alginate Impression Material	Alginate Impression Material
Classification Name	Impression Material, Dental	Impression Material, Dental	Impression Material, Dental
Class	2	2	2
Product Code	ELW	ELW	ELW
Storage	Store at room temperature.	Store at room temperature.	Store at room temperature.
Indications for Use	Identic Alginate Dental Impression Materials are irreversible hydrocolloids for dental impressions used by the dentist to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define the required interventions and/or check their effectiveness. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.	KromaFaze Alginate Dental Impression Materials are irreversible hydrocolloids for dental impressions used by the dentist to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define the required interventions and/or check their effectiveness. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.	Image Alginate Dental Impression Materials are irreversible hydrocolloids for dental impressions used by the dentist to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define the required interventions and/or check their effectiveness. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.
Setting Mechanism	Reaction of alginates and calcium sulfate with water	Reaction of alginates and calcium sulfate with water	Reaction of alginates and calcium sulfate with water

Element	Predicate Identic Alginate (K160441)	Predicate KromaFaze Alginate (K160441)	Proposed Image Alginate (K160097)
Color Change	No	Yes	No
Material Compatibility	Biocompatibility meets requirements	Biocompatibility meets requirements	Biocompatibility meets requirements
Shelf Life	24 months based on real time data	24 months based on real time data	24 months based on real time data
Mixing time per ISO	Pass 30"	Pass 30"	Pass 30"
Working time per ISO 1563	Pass 2'20" (Regular Set)	Pass 2'20" (Regular Set)	Pass 2'20" (Regular Set)
	Pass 1'45" (Fast Set)	Pass 1'45" (Fast Set)	Pass 1'45" (Fast Set)
	Pass 1'15" (Extra Fast Set)		
Setting time per ISO 1563	Pass ≤3'30" (Regular Set)	Pass ≤3'30" (Regular Set)	Pass ≤3'30" (Regular Set)
	Pass ≤2'20" (Fast Set)	Pass ≤2'20" (Fast Set)	Pass ≤2'20" (Fast Set)
	Pass ≤2'00" (Extra Fast Set)		
Homogeneous Mixed Material ISO 1563	Pass	Pass	Pass
Compatibility with gypsum and reproduction of detail (µm) ISO 1563	Imparts a smooth surface to, and separates cleanly from, a gypsum cast. Impression reproduces 50 µm line. Pass	Imparts a smooth surface to, and separates cleanly from, a gypsum cast. Impression reproduces 50 µm line. Pass	Imparts a smooth surface to, and separates cleanly from, a gypsum cast. Impression reproduces 50 µm line. Pass
Recovery from deformation (%) per ISO 1563	≥95% Pass	≥95% Pass	≥95% Pass

Element	Predicate Identic Alginate (K160441)	Predicate KromaFaze Alginate (K160441)	Proposed Image Alginate (K160097)
Compressive strength per ISO 1563	≥0.35 MPa Pass	≥0.35 MPa Pass	≥0.35 MPa Pass
Dimensional Changes at 100 hours	≤ 2% when compared to a Mold Pass	≤ 2% when compared to a Mold Pass	≤ 2% when compared to a Mold Pass
Configurations/ Dimensions	1 lb. (454 g) bag and a singles pack of 18 g	1 lb. (454 g) bag and a singles pack of 18 g	1 lb. (454 g) bag and a singles pack of 18 g
Method of Mixing	Mixing of powder with water	Mixing of powder with water	Mixing of powder with water
Flow Properties	N/A as the material is a powder that sets upon mixing with water. The property does not apply to Alginates, only to impression pastes.	N/A as the material is a powder that sets upon mixing with water. The property does not apply to Alginates, only to impression pastes.	N/A as the material is a powder that sets upon mixing with water. The property does not apply to Alginates, only to impression pastes.
Viscosity	Not Applicable; as the material is a powder that sets upon mixing with water. Viscosity property does not apply to Alginates, only impression pastes.	Not Applicable; as the material is a powder that sets upon mixing with water. Viscosity property does not apply to Alginates, only impression pastes.	Not Applicable; as the material is a powder that sets upon mixing with water. Viscosity property does not apply to Alginates, only impression pastes.
Wettability	N/A as the material is a powder that sets upon mixing with water. The property does not apply to Alginates, only to impression pastes.	N/A as the material is a powder that sets upon mixing with water. The property does not apply to Alginates, only to impression pastes.	N/A as the material is a powder that sets upon mixing with water. The property does not apply to Alginates, only to impression pastes.
Working Humidity	Working/Setting Time per ISO 1563 is tested in humidity chamber at release	Working/Setting Time per ISO 1563 is tested in humidity chamber at release	Working/Setting Time per ISO 1563 is tested in humidity chamber at release

Chemical Composition	Function	Predicate Identic Alginate (K160441)	Predicate KromaFaze Alginate (K160441)	Proposed Image Alginate (K160097)
Dicalite speedex	Filler	70 – 80 %	70 – 80 %	70 – 80 %
Magnesium oxide	Modifier and Filler	<1 %	<1 %	<1 %
Sodium benzoate	Anti-Microbial and Preservative	<1 %	<1 %	<1 %
Zinc Borate	Anti-Microbial and Preservative	<2 %	<2 %	<2 %
Potassium titanium fluoride	Surface for Gypsum	1.5 – 3.5 %	1 – 3 %	1.5 – 3.5 %
Tetra sodium pyrophosphate	Retarder to Adjust Set Time	<2 %	<1 %	<2 %
Potassium alginate	Reactant	3 – 8 %	3 – 8 %	3 – 8 %
Potassium alginate Kimica	Reactant	3 – 8 %	3 – 8 %	3 – 8 %
Terra Alba (gypsum)	Reactant	3 – 8 %	3 – 8 %	3 – 8 %
Mineral Oil	Reduction of Dusting	<2 %	<2 %	<2 %
Xanthan gum	Thickening Agent	N/A	<2 %	N/A
Trisodium phosphate	Emulsifier and Thickening Agent	N/A	<2 %	N/A
Phenolphthalein	pH Indicator Causing Color Change Above ≈ 10.0 pH	N/A	<1 %	N/A
Thymophthalein	pH Indicator Causing Color Change Above ≈ 10.5 pH	N/A	<1 %	N/A
Pigment signal green	Coloring	N/A	N/A	<2 %
Pigment rocket red	Coloring	<1 %	N/A	N/A
Flavor natural mint	Flavoring Agent	N/A	<1 %	<1 %
Flavor cinnamon	Flavoring Agent	<1 %	N/A	N/A

Clinical Performance Data

Clinical performance testing has not been performed for Image Alginate Dental Impression Materials.

Intended Use

The Intended Use for Image Alginate Dental Impression Materials is identical to that for the predicate, Identic Alginate and KromaFaze Alginate product lines (K160441).

Image Alginate Dental Impression Materials are irreversible hydrocolloids for dental impressions used by the dentist to take the anatomical data of the patient's mouth and subsequently realize a plaster mold useful to diagnose problems, define the required interventions and/or check their effectiveness. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.

Conclusion as to Substantial Equivalence

The technological characteristics of Image Alginate are very similar to KromaFaze and Identic Alginate (K160441). The intended uses of the proposed and predicate products are identical. The only major differences between KromaFaze, Identic, and Image are in a color changing feature and flavorings. These proposed product Image Alginate has an equivalent chemical principle of function, setting mechanism, and have identical delivery systems as compared to the predicate. The proposed and predicate products also share similarities in mechanism of action, preparation times, and select performance characteristics relevant to impression materials. The proposed Image Alginate Impression Materials are substantially equivalent to Identic and KromaFaze Alginate Impression Materials (K160441) based on the design, performance, biocompatibility testing, and the intended use. Any noted differences in technological characteristics between the proposed and predicate products do not affect the intended use, do not raise new questions of safety and effectiveness, and demonstrate the proposed product is at least as safe and effective as the legally marketed predicate device. Based on this reasoning and the results of performance testing based on ISO 1563:1990 and biocompatibility testing, Image is substantially equivalent to the predicate, Identic and KromaFaze Alginate (K160441).