



Food and Drug Administration
10903 New Hampshire Avenue
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October 28, 2015

Cavex Holland Bv
Mr. Richard Woortman
Manager Technical Services
Fustweg 5
Haarlem, 2031CJ
The NETHERLANDS

Re: K151535
Trade/Device Name: Cavex Cream Alginate
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: September 25, 2015
Received: September 28, 2015

Dear Mr. Woortman:

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

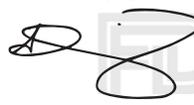
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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

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

510(k) NUMBER (IF KNOWN) : K15xxxxx K151535

DEVICE NAME :

Cavex Cream Alginate
Alginate Impression Materials

INDICATIONS FOR USE :

Cavex Cream Alginate is an irreversible hydrocolloid dental impression material used by the dentist for taking impressions of the oral cavity with the purpose of constructing a gypsum cast that is a copy of the situation in the mouth. It is a general purpose impression materials for making study models, first impressions for the construction of individual trays, situation models, orthodontic impressions.

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (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)

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Submitter/Manufacturer: **Cavex Holland BV**
 Establishment: Fustweg 5, 2031CJ Haarlem, The Netherlands
 Registration number: 9614573
 Owner/operator number: 9033296
 Primary Contact Person: Richard Woortman
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 Cavex Holland BV
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Device:
 Trade name: Cavex Cream Alginate
 Common use: Impression Material
 Classification Names: Material, Impression
 Regulation Number: CFR 872.3660
 Product Code: ELW
 Primary Predicate: K051207 Cavex Holland Cavex Orthotrace
 Secondary Predicate: K011419 Cavex Holland Cavex ColorChange

Device Description: Cavex Cream Alginate impression material is an impression material with a creamy consistency for general dental practice and for orthodontics. It is presented in the form of a purple colored powder with bubble gum flavor.

Comparison of
 Indications for Use:

K151535 Cavex Holland BV - Cavex Cream Alginate
 Cavex Cream Alginate is an irreversible hydrocolloid dental impression material used by the dentist for taking impressions of the oral cavity with the purpose of constructing a gypsum cast that is a copy of the situation in the mouth. It is a general purpose impression materials for making study models, first impressions for the construction of individual trays, situation models, orthodontic impressions.

K051207 Cavex Holland BV - Cavex Orthotrace
 Cavex Orthotrace alginate impression material is a dental impression material based on alginate. It is used for taking impressions of the oral cavity with the purpose of constructing a gypsum cast that is a copy of the situation in the mouth. Cavex Orthotrace has an extra fast setting time, high elasticity, high tear resistance, can be poured twice with gypsum and is presented in an attractive fuchsia-coloured powder with a red-fruit flavour. Therefore, Cavex Orthotrace is particularly suited for orthodontics

K011419 Cavex Holland BV - Cavex ColorChange

Cavex ColorChange is a dental impression material based on alginate. It is used for taking impressions of the oral cavity with the purpose of constructing a gypsum cast that is a copy of the situation in the mouth. It is a general purpose impression material for making study models, first impressions for the construction of individual trays, situation models, orthodontic impressions, etc.

Cavex ColorChange has the special characteristic of being a color-changing alginate: it becomes violet upon contact with water in the mixing bowl, changes to pink indicating the end of the mixing time and then finally changes to white indicating the end of the setting time in the mouth.

Indications for UseDiscussion:

Cavex Cream Alginate is comparable to other irreversible hydrocolloid impression materials on the market, such as Cavex Orthotrace (K051207) and Cavex ColorChange (K011419). The devices have the same intended use and – except for minor differences in composition to achieve certain features such as rapid setting or changes in color – employ the same alginate-based hydrocolloid chemistry. All three products may be employed in the same clinical applications. The difference between Cavex Cream Alginate and the declared predicate devices lie in the selection and relative percentages of the additives, all of which are common for irreversible-hydrocolloid impression materials.

Technical Characteristics:

The technology for the proposed device Cavex Cream Alginate is comparable to the predicate device. Basically the alginate, a soluble salt of alginic acid (extracted from brown seaweed), serves as the thickener for water. It reacts chemically with calcium sulphate to make the paste harden into a solid impression. The fillers (diatomaceous earth) give the mixture its mechanical strength. A retarder, sodium pyrophosphate, is used for achieving the required hardening-time, sufficient to mix, apply and take a proper impression and setting time in the mouth. Besides, stabilizers and pigments are added.

Performance Data:

Physical Parameters	Proposed device	Primary device	Secondary device	ADA18 Requirements
	K151535	K051207	K011419	
	Cavex Holland	Cavex Holland	Cavex Holland	
	Cavex Cream	Cavex Orthotrace	Cavex ColorChange	
Appearance	Powder	Powder	Powder	
Color	Purple	Fuchsia	Fuchsia	
Flavor	bubble-gum	red-fruit	red-fruit	
Compatibility & Detail Reproduction	Complies	Complies	Complies	0 - 50 µm
Recovery from Deformation	96	96	96	>95 %
Strain in Compression	16	16	16	5 - 20 %
Compressive Strength	> 0.80	>0.80	>0.80	> 0.35 Mpa
Deterioration	> 0.60	> 0.60	> 0.60	> 0.294 MPa

Biocompatibility:

The proposed device Cavex Cream Alginate impression material, the primary predicate device and the secondary device contacts directly with the oral mucosa (3 – 5 minutes) therefore they are categorized as surface contact devices with limited contact duration. Testing was performed for cytotoxicity (ISO 10993-5), sensitization and irritation (ISO10993-10). The test results demonstrated that the proposed device Cavex Cream Alginate is biocompatible.

Conclusion:

The technical characteristics, material composition, principles of operation and indications for use of the proposed device Cavex Cream Alginate (K151535) is comparable to the predicate device. Therefore, Cavex Holland BV considers that Cavex Cream Alginate Impression Material is substantially equivalent to the predicate device.



Richard Woortman
Manager Technical Services
Cavex Holland BV