



Food and Drug Administration  
10903 New Hampshire Avenue  
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Hygedent Inc.  
Peng Wang  
General Manager  
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Changping District 102211  
Beijing, 102211 CHINA

July 26, 2017

Re: K170812  
Trade/Device Name: HygePLUS Alginate Impression Material  
Regulation Number: 21 CFR 872.3660  
Regulation Name: Impression Material  
Regulatory Class: Class II  
Product Code: ELW  
Dated: April 20, 2017  
Received: May 5, 2017

Dear Peng Wang:

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,

  
Mary S. Runner -S

for

Lori Wiggins, MPT, CLT

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Chapter 5 Indications for Use Statement

### INDICATIONS FOR USE STATEMENT

510(K) Number if known:K170812

Device Name: HygePLUS Alginate Impression Material

Indications For Use:

HygePLUS Alginate Impression Material is irreversible hydrocolloids for dental Impressions used by the dentist to take the anatomical data of the patient's mouth. The device is Intended to provide models for study and for production of restorative prosthetic devices, such as gold Inlays and dentures.

Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  
(21 CFR 801Subpart C)

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NEEDED

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

## 510(k) Summary

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

**Date:** 03/10/2017  
**Submitter:** HYGEDENT INC  
**Add :** Daliushu Industrial Zone Xiaotangshan Changping District  
Beijing102211, P. R. China

### Establishment

**Registration Number:** 3011187729  
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**Device:Trade Name :** HygePLUS Alginate Impression Material

### Common/Usual

**Name:** Impression Material

**Classification Names:** Material, Impression

**Regulation number:** 21 CFR 872.3660

**Product Code:** ELW

**Predicate Device(s):** Primary Predicate Device:  
K140074 : Hygedent Inc. Hygedent Alginate Impression Material  
Reference Predicate Device:  
K023466 : Cavex Holland Tulip Alginate Impression Material

**Device Description:**

HygePLUS Alginate Impression Material is a alginate impression material for general dental practice and for orthodontics. It is presented in the form of a homogeneous yellow powder with spearmint flavour.

**Comparison of**

**Indications for Use:** HygePLUS Alginate impression Material is irreversible hydrocolloids for dental impressions used by the dentist to take the anatomical data of the patient's mouth. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.

K140074: Hygedent Alginate Impression Material is irreversible hydrocolloids for dental Impressions used by the dentist to take the anatomical data of the patient's mouth. The device Is Intended to provide models for study and for production of restorative prosthetic devices, such as gold Inlays and dentures.

K023466 : Tulip 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 . It is a general purpose impression material for making study models, first impressions for the construction of

individual trays, situation models, orthodontic impressions etc.

**Indications for Use**

**Discussion:**

HygePLUS Alginate impression Material is comparable to other irreversible hydrocolloid impression materials on the market, such as Hygedent Alginate Impression Material (k140074) and Tulip Alginate impression material (k023466). The devices have the same intended use and except for minor differences in composition to achieve certain features such as rapid setting or elasticity, tear resistance employ the same alginate-based hydrocolloid chemistry. All three products may be employed in the same clinical applications. The difference between HygePLUS Alginate impression Material 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.

**Technology**

**characteristics:**

The technology for the proposed device HygePLUS Alginate impression Material is comparable to the predicate device. Basically the alginate, a soluble salt of alginate (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.

**Technological characteristics**

**Discussion:** Proposed device and Primary Predicate Device (K140074), have the same raw materials,except for minor differences in proportion. This difference does not affect the safety and effectiveness.

**Performance data:** The physical properties of the proposed device and the predicate device are compared as following:

Physical Parameters	Proposed device	Primary predicate device	Reference predicate device	ADA18 Requirements
	K170812	K140074	K023466	
	Hygedent Inc.	Hygedent Inc.	Cavex holland	
	HygePLUS	Hygedent	Tulip	
Appearance	Powder	Powder	Powder	
Color	Yellow	Red	Yellow	
Flavor	spearmint flavor	Mint flavor	Mint flavor	
Compatibility with gypsum	complies	complies	complies	0-50µm
Elastic recovery	97.4%	96.50 %	96%	> 95%
Strain in compression	16%	14.70%	14%	5-20%
Compressive strength	1.00 MPa	0.75 MPa	0.7 MPa	> 0.35MPa

**Performance tests Discussion:**

Although there is little difference for Elastic recovery, Strain in compression, Compressive strength of Proposed device and Primary Predicate Device(K140074), Reference Predicate Device(K023466), they comply with ADA Spec No.18 recommendations. This difference does not affect the safety and effectiveness.

**Summary of Non-Clinical Tests:**

Performance testing was conducted to validate and verify that the proposed device met all design specifications and was substantially equivalence to the predicate device.

Results of performance testing indicate that the grounding pad meets applicable sections of

the standards referenced and are sufficient for their intended use. The subject of this premarket submission, HygePLUS Alginate Impression Material did not require clinical studies to support substantial equivalence.

**Biocompatibility :**

HygePLUS Alginate Impression Material, the primary predicate device and Reference Predicate Device contacts directly with the oral mucosa (3-5 minutes). The duration of contact is less than 24 hours, therefore they are categorized as surface contact devices with limited contact duration. Testing was Performed for cytotoxicity (ISO 10993-5 ),sensitization and irritation( ISO 10993-10).The test results demonstrate that the proposed device HygePLUS Alginate Impression Material is biocompatible .

**Conclusion:**

The technical characteristics, material composition, principles of operation and indications for use of the proposed device HygePLUS Alginate impression Material is comparable to the predicate device. The few differences do not affect the safety and effectiveness of the proposed device. Therefore, Hygedent Inc. considers that HygePLUS Alginate impression Material is substantially equivalent to the predicate device.