MAY 2 1 2014

K140074

510(k) Summary

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

Date:	2014 Jan 04
Submitter:	HYGEDENT INC. Add: Daliushu Industrial Zone Xiaotangshan Changping District, 102211, Beijing, P. R. China
Primary Contact Person:	Peng Wang General Manager HYGEDENT INC. Tel: +86-13901284956 Fax: +86-10-60701780
Secondary Contact Person:	Mike Gu Regulatory Affairs Manager OSMUNDA Medical Device Consulting Co., Ltd. Tel: (+86)-20-6232 1333 Fax: (+86) -20-8633 0253
Device: Trade Name	Hygedent Alginate Impression Material
Common/Usual Name:	Impression Material
Classification Names:	Material, Impression
Regulation number:	CFR 872.3660
Product Code:	ELW
Predicate Device(s):	K023466
Device Description:	Hygedent Alginate Impression Material is a dust free alginate impression material with a creamy consistency for general dental practice and for orthodontics. It is presented in the form of a homogeneous orange colored powder with a nice mint flavor. The material has exceptional good elastic properties and a high tear-resistance. The impression surface is very smooth, which gives excellent gypsum compatibility.
Intended Use:	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.

Technology:

All the alginates described in the premarket notification application (510k) have the following technological characteristics:

* Identical mechanism of action
* Highly similar preparation times
* Highly similar elastic recovery and accuracy

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

Physical Parameters	Proposed device	Predicate device
Appearance	Powder	Powder
Odor	Peppermint	Peppermint
Compression strength	0.75MPa	0.7 MPa
Compatibility with gypsum	50μm	50μm
Recovery from Deformation	96.50 %	96%

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

Hygedent Alginate Impression Material contacts directly with the oral mucosa. The duration of contact is less than 24 hours. Biocompatibility of the Material complies with ISO 10993-5 and ISO 10993-10. The test results demonstrate that the proposed device is biocompatible.

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

- ISO 1563:1990;
- ADA Specification No.18:1992;

Results of performance testing indicate that the grounding pad meets applicable sections of the standards referenced and are safe and as effective for their intended use. The subject of this premarket submission, Hygedent Alginate Impression Material, did not require clinical studies to support substantial equivalence.

Conclusion:	HYGEDENT INC. considers the Hygedent Alginate Impression Material to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2014

HYGEDENT, Incorporated
Ms. Peng Wang
General Manager
Daliushu Industrial Zone Xiaotangshan, Changping District
Beijing 102211
P.R. CHINA

Re: K140074
Trade/Device Name: Hygedent Alginate Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: February 19, 2014
Received: February 21, 2014

Dear Ms. 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" (21CFR 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting 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): [] K140074

Device Name: Hygedent Alginate Impression Material

Common/usual name: Impression Material

Indications for Use:

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.

Prescription Use _X_	OR	Over-The-Counter Use_
(Part 21 CFR 801 Subpart D)		(Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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