September 4, 2019

Hygedent Inc.
Peng Wang
General Manager
Room 210C, Building 4, No 5 Chaoqian Road,
Science Industry Park, Changping
Beijing, 102299 Cn

Re: K191034
Trade/Device Name: VPS Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: March 20, 2019
Received: April 18, 2019

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. 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,

for Michael Adjodha
Acting Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191034

Device Name
VPS Impression Marterial

Indications for Use *(Describe)*
VPS Impression Material is intended for use with all crowns, bridges, occlusal and dental implant impression techniques to reproduce the structure of a patient's teeth and gums.

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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Chapter 6 510(k) Summary

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

Date:	03/20/2019
Submitter:	
Add：	HYGEDENT INC Room 210C , Building 4 , No 5 Chaoqian Road , Science Industry Park , Changping District , Beijing, P.R.China
Establishment	
Registration Number:	3011187729
Owner/Operator Number:	10047045
Primary Contact Person:	Peng Wang (General Manager) HYGEDENT INC. Tel: +85-13901284956 email： zoe.sun@hygedent.com
US Agent:	RICHARD TING TING ORTHODONTIC LAB,INC 2138 South Broad Street Philadelphia Phila , PA 19145 Phone: 215 4688168 Ext Fax: 215 4685335 Email: Tingdental@Yahoo.Com
Device:Trade Name：	VPS 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: K040053:Discus Dental,Inc . Precision VPS Impression Material Reference Predicate Device: K133071: Shandong Huge Dental Material Corporation Elastomeric Impression Material
Device Description:	VPS Impression Material is dental Impression Material . It complies with the requirements of ISO 4823:2015 for dental elastomeric impression materials. It is supplied as atwo-part base/catalyst formulation preloaded in a dual-barrel cartridge. The VPS Impression Material package includes four dual-barrel 50ml cartridges.
Comparison of Indications for Use:	VPS Impression Material is intended for use with all crowns, bridges, occlusal and dental implant impression techniques to reproduce the structure of a patient's teeth and gums. K040053: Precision VPS Impression Material is intended for use with all crowns, bridges, occlusal and dental implant impression techniques to reproduce the structure of a patient's teeth and gums. K133071：A Silicone Dentistry-Elnstie Impression Material, with the trade name of PERFIT. is an addition-cure vinyl polysiloxanec dental impression material that is used far all crown and bridge, edentulous. orthodontic and implant impression techniques.

Indications for Use

Discussion: VPS Impression Material Is comparable to other vinyl Polysiloxane dental impression materials on the market, such as Precision VPS Impression Material (K040053) and Elastomeric Impression Material (k133071).the devices have the same intended use and except for minor differences in composition to achieve certain features such as rapid setting or elasticity, Strain-in-compression employ the same vinyl Polysiloxane chemistry. All three products may be employed in the same clinical applications. The difference between VPS Impression Material and the declared predicate devices lie in the selection and relative percentages of the additives, all of which are common for vinyl Polysiloxane impression materials.

Technology characteristics: The technology for the proposed device VPS Impression Material is comparable to the predicate device.VPS Impression Material is mainly composed of Vi-PDMS, Hydrogen-containing Silicone Oil, Catalyst, Inhibitor, Silica Powder and Filler. Vi-PDMS is used as the base polymer, Hydrogen-containing Silicone Oil as a crosslinking agent, Pt Catalyst as catalysts, Silica Fume is used as filler, Fumed Silica can be used as a filler for reinforcements. Besides, Inhibitor, Thinner, Pigments are added.

Technological characteristics

Discussion: Proposed device and Primary Predicate Device（K040053), 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	Standard ISO4823
	K191034	K040053	K133071	
	Hygedent Inc.	Discus Dental,Inc .	Shandong Huge Dental Material Corporation	
	VPS Impression Material	Precision VPS Impression Material	Elastomeric Impression Material	
Consistency	31	32	31	≤35mm
Working time	2′	1′45″	2′	≥1′30″
Detail reproduction	complies	complies	complies	50μm
Linear dimensional change	0.16%	0.18%	0.20%	≤1.5%
Compatibility with gypsum	complies	complies	complies	50μm
Elastic recovery	99.06%	99.0%	98.98%	≥96.5%
Strain-in-compression	2.73%	2.38%	3.12%	≥0.8%,≤20%

Performance tests

Discussion: Although there is little difference for Consistency, Working time, Linear dimensional change Elastic recovery, Strain in compression of Proposed device and Primary Predicate Device(K040053), Reference Predicate Device(K133071), they are complied with Standard ISO4823 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,VPS Impression Material did not require clinical studies to support substantial equivalence.

Biocompatibility：

VPS 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 Cytoxicity (ISO 10993-5), Sensitization and Irritation(ISO 10993-10).The test results demonstrate that the proposed device VPS Impression Material is biocompatible .

Conclusion:

The technical characteristics, material composition, principles of operation and indications for use of the proposed device VPS 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 VPS Impression Material is substantially equivalent to the predicate device.