April 19, 2021

Hygedent, Inc.
Peng Wang
General Manager
Room 210C, Building 4, No 5 Chaoqian Road
Beijing, 102299
CHINA

Re: K203824
Trade/Device Name: VPS Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: January 25, 2021
Received: January 25, 2021

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,

Michael E. Adjodha, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203824

Device Name
VPS Impression Marterial

Indications for Use *(Describe)*
VPS Impression Material(Light Body) is to be used as syringeable impression materials for:
-Two-step putty-wash impression technique;
-One-step putty-wash impression technique;
- Two-step impression technique using dual viscosities ;
- Reline impressions ;
-Fabricating full or partial 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.

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Chapter 6 510(k) Summary (K203824)

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

Date:	04/16/2021
Submitter:	HYGEDENT INC
Add:	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:	Zoe HYGEDENT DENTAL INC. 11622 El Camino Real, Suite 100, San Diego, CA 92130 Phone: 858 764 2495 Email: zoesunyi@yahoo.com
Device:Trade Name:	VPS Impression Material
Type:	Light
Common/Usual Name:	Impression Material
Classification Names:	Material, Impression
Regulation number:	21 CFR 872.3660
Product Code:	ELW
Regulation Class:	2
Predicate Device(s):	K192941 (Primary Predicate): Osstem Implant Co.,Ltd. HySil Super Fast Impression Materials

Device Description: K203824: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.

Indications for Use: K203824： VPS Impression Material(Light Body) is to be used as syringeable impression materials for:

-Two-step putty-wash impression technique;

-One-step putty-wash impression technique;

- Two-step impression technique using dual viscosities ;

- Reline impressions ;

-Fabricating full or partial dentures;

Substantial Equivalence Matrix ：

	Proposed Device	**Primary Predicate Device**	**Remark**
Device Name	VPS Impression Material	HySil Super Fast Impression Materials	Different
Type	Light	Heavy, Mono, Light	Different
510(k) No.	K203824	K192941	Different
Manufacturer	HYGEDENT INC	Osstem Implant Co.,Ltd.	Different
Indications for Use:	**VPS Impression Material (Light Body)** is to be used as syringeable impression materials for: -Two-step putty-wash impression technique; -One-step putty-wash impression technique; - Two-step impression	**HySil Heavy Super Fast** is to be used as heavy-bodied materials for: - One-step impression technique using single or dual viscosities; - Two-step impression technique using dual viscosities - Functional impressions **HySil Mono Super Fast** is to be used as a medium bodied tray or	Different since the predicate devices have 3 types of devices (Heavy, Mono,Light), while the proposed devices have 1type

	technique using dual viscosities ; - Reline impressions ; - Fabricating full or partial dentures;	syringeable impression material for: - Taking impressions over removable/ fixed restorations and implants - Functional impressions - Fabricating crown and bridgework or inlays - Fabricating full or partial dentures - Reline impressions - Use in the simultaneous mixing technique as well as the putty-wash and triple tray techniques - Transferring root posts when fabricating posts and cores indirectly **HySil Light Super Fast** is to be used as syringeable impression materials for: -Two-step putty-wash impression technique; -One-step putty-wash impression technique; - Two-step impression technique using dual viscosities ; - Reline impressions ; - Fabricating full or partial dentures;	of devices . Although there are differences in number of types, the Indications for Use Statements of **Light type** for both proposed and predicate devices are same.

Principle of Operation	- Be placed on an impression tray (or injected directly into the mouth, depending on the technique and device) and used to reproduce the structure of a patient's teeth and gums - Provide models for study and for production of restorative prosthetic devices	- Be placed on an impression tray (or injected directly into the mouth, depending on the technique and device) and used to reproduce the structure of a patient's teeth and gums - Provide models for study and for production of restorative prosthetic devices	Same
Description of Material	Vinylpolysiloxane	Vinylpolysiloxane	Compose with same affiliated material, but ratios of each component in use are different
Standard Conformed	ISO 4823	ISO 4823	Same
Working Time	1 min. 30 sec.	Over 1 min. 15 sec	Proposed devices have longer working time
Shelf-life	2 years	2 years	Same

S.E	**Similarities:** The proposed devices and the predicated devices are made with same affiliated material called Vinylpolysiloxane conformed to ISO 4823 standard. Both are in 50ml cartridge with base and catalyst ratio of 1 to 1; have same indications for use; have same principle of operation; and have same shelf-life. **Differences** Compared to the predicated devices, the proposed devices have different composition ratios which results in longer working time. However, based on the results of the performance and the biocompatibility testing, the proposed and the predicated devices both passed the requirements. Also, there are differences in Indications for Use Statement since the predicated devices have 3 types of devices, Heavy, Mono and Light while the proposed devices have 1 types of devices. Although there are differences in number of types, the Indications for Use Statements of Light type for both proposed and predicated devices are same. Thus, the differences in Indications for Use Statement do not affect the substantial equivalence of proposed devices. Therefore, we stated that proposed devices (VPS Light Impression Materials) are substantially equivalent to the predicated devices (HySil Light Super Fast Impression Materials) cleared in K192941.

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 proposed device and predicate device contacts directly with the oral mucosa (3-5 minutes). The duration of contact is less than 24hours, 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 VPS Impression Material is as biocompatible as the predicate device.

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.