HRS Co., Ltd.
% Yang Ho Dong
CEO
Onbix Corporation
#821 Samil Plaza, 14 Dogok-ro 1-gil, Gangnam-gu
Seul, 06253 KOREA

November 28, 2018

Re: K181604
Trade/Device Name: Sildent Fast Light Body, Sildent Fast Heavy Body, Sildent Bite
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: August 22, 2018
Received: August 31, 2018

Dear Yang Ho Dong:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2018.11.28 11:39:11 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
not yet assigned K181604

Device Name
Sildent Fast Heavy Body
Sildent Fast Light Body
Sildent Bite

Indications for Use *(Describe)*
to obtain 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.

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510(k) SUMMARY K181604

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information: **HRS Co., Ltd.**
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Date Summary Prepared: Aug 22, 2018

Device Information:

Trade Name(s):	Sildent Fast Heavy Body, Sildent Fast Light Body, Sildent Bite
Classification Name:	impression material
Panel:	dental
Product Code & Regulation:	ELW / 872.3660

Predicate Device Information:
K882690 3M Imprint
K024034 Zhermack Occulfast Rock

Device Description:
Vinyl polysiloxane is an addition-reaction silicone elastomer (an addition silicone). It is a viscous liquid that cures quickly into a rubber-like solid, taking the shape of whatever surface it was lying against while curing. As with 2-part epoxy, its package keeps its 2 component liquids in separate container until the moment they are mixed and applied, because once mixed, they cure (harden) rapidly.
To create the material, the user simply mixes the base with the catalyst, and the chemical reaction begins. Once the impression material is set and slightly modified, it is taken to patient′'s mouth for use in the transfer bonding process.

Indications for Use:
to obtain the structure of a patient's teeth and gums

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

* indications for use
* technological characteristics
* performance properties

Summary of the technological characteristics compared to the predicate device
new device is substantially equivalent to the predicate device in its technological characteristics stated in the comparison table as below.

<Sildent Fast Heavy Body / Sildent Fast Light Body>

	HRS Co.,Ltd	3M ESPE (K882690)
Model	Sildent	Imprint 3 Quick Step
Type	Type 1: Fast Heavy Body Type 2: Fast Light Body	Type 1 : Quick Step Heavy Body Type 3 : Quick Step Light Body
Intended Use	to obtain the structure of a patient's teeth and gums.	to obtain the structure of a patient's teeth and gums.(Identical)
Applied standard	ISO4823	ISO4823 (Identical)
Recovery form deformation	>96.5%	> 99.0% (Similar)
	This meets the applicable standard ISO4823 standard > 96.5%	
Strain in compression	<10% (Fast Heavy) <10% (Fast Light)	< 10% (Quick Step Heavy) < 10% (Quick Step Light)
Linear dimensional change	<1.5% (Fast Heavy) <1.5% (Fast Light)	< 0.3% (Quick Step Heavy) < 0.3% (Quick Step Light)
	This meets the applicable standard ISO4823 standard < 1.5%	
Working time	1 min 30sec (Fast Heavy) 1 min 15sec (Fast Light)	1 min 15 sec (Quick Step Heavy) 1 min 30 sec (Quick Step Light)
	The curing time of both devices is similar	

Intraoral setting time	3 min (Fast Heavy) 3 min (Fast Light)	2 min 30 Sec (Quick Step Heavy) 2 min 30 Sec (Quick Step Light)
	The curing time of both devices is significantly reduced compared to regular products	

<Sildent bite>

	HRS Co., Ltd.	**Zhermack (K024034)**
model	Sildent Bite	Occulfast Rock
color	lilac	White Yellow
Base/Catalyst mixing ratio	1:1	1:1
Working time	30sec	30sec
Time in mouth	60sec	60sec
hardness	More than 20HD	95 shore A
	The subject device is developed for standard> 20 HD in Bite's standard DIN 13903. The difference between the two devices is simply the difference of measurement method and does not affect safety and effectiveness.	

Non-Clinical Study performance
To be in compliance with electromagnetic safety and compatibility, appropriate study has been applied to the new device in accordance with the following standard

ISO 10993-5 cytotoxicity
ISO 10993-10 skin irritation, sensitization
ISO 10993-11 systemic toxicity

Conclusion
New device has the same device characteristics as the predicate device,
Based on the information provided in this summary we conclude that New device is substantially equivalent to the predicate device K882690 3M Imprint / K024034 Zhermack Occulfast Rock.