November 7, 2022

HDI, Inc.
Taekyou Kim
CEO
A-1504, 14, Sagimakgol-ro, 45 Beon-gil, Jungwon-gu
Seongnam-si, Gyeonggi-do 13209
SOUTH KOREA

Re: K222741
Trade/Device Name: DENU Light Body(Regular, Fast), DENU Heavy Body(Regular, Fast), DENU Putty Set(Regular, Fast)
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: August 25, 2022
Received: September 9, 2022

Dear Taekyou Kim:

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 -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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)*
K222741

Device Name
DENU Light Body(Regular, Fast)
DENU Heavy Body(Regular, Fast)
DENU Putty Set(Regular, Fast)

Indications for Use *(Describe)*
DENU Light Body(Regular, Fast) / DENU Heavy Body(Regular, Fast)

- Crown and bridge impression
- Inlay and onlay impression
- Denture impression
- Model impression

DENU Putty Set(Regular, Fast)
- Crown and bridge impression
- Inlay and onlay impression

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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006_ 510(k) SUMMARY

Date: August 25, 2022

1. SUBMITTER

HDI, Inc.
A-1504, 14, Sagimakgol-ro, 45 Beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea
TEL : +82-31-735-3510
FAX : +82-31-735-3511
Contact Name: Taekyou Kim
Email: hdikorea@hanmail.net

2. DEVICE

·Trade Name: DENU Light Body(Regular, Fast)
DENU Heavy Body(Regular, Fast)
DENU Putty Set(Regular, Fast)

·Common Name: Impression Material

·Regulation Number 872.3660

·Class: 2

·Classification Product Code: ELW

3. PREDICATE DEVICE

DENU Light Body(Regular, Fast), DENU Heavy Body(Regular, Fast)
: K152615 Vonflex S™, Vericom Co. Ltd
DENU Putty Set(Regular, Fast)
: K152518 Vonflex S Putty, Vericom Co. Ltd

4. DEVICE DESCRIPTION

The DENU family of silicone impression materials consists of three different viscosities (light body, heavy body, putty) for various application systems. Products are further

classified into Regular type and Fast type, depending on curing time, but there is no difference on viscosity, indications for use, or scope of use.

Each device is consisted of 1:1 base and catalyst component, packaged in 560mL jars for DENU Putty set and 50mL syringes for other devices.

5. INDICATIONS FOR USE

DENU Light Body(Regular, Fast) / DENU Heavy Body(Regular, Fast)

- Crown and bridge impression
- Inlay and onlay impression
- Denture impression
- Model impression

DENU Putty Set(Regular, Fast)

- Crown and bridge impression
- Inlay and onlay impression

6. NON-CLINICAL TESTING

The following test articles were tested based on the referenced standard. All the test results met the preset test criteria.

- ISO 4823 – Appearance and Component colors, Consistency, Working time, Detail reproduction, Setting time, Compatibility with gypsum, Linear dimensional change, Elastic recovery, Strain in compression
- ISO 7405 - Cytotoxicity
- ISO 10993-10 - Skin sensitization, Oral mucosa irritation
- ISO 10993-11 - Acute systemic toxicity

7. SUBSTANITAL EQUIVALENCE

	Subject device	Predicate Device	Discuss/Justify the Differences
510(k) Number	New	K152615	-

Trade Name	DENU Light Body(Regular, Fast) DENU Heavy Body(Regular, Fast)	Vonflex S™	-
Manufacturer	HDI, Inc.	Vericom Co. Ltd	-
Common Name	Impression material	Impression material	Same
Device Class	2	2	Same
Product Code	ELW	ELW	Same
Device Description	The DENU family of silicone impression materials consists of three different viscosities (light body, heavy body, putty) for various application systems. Products are further classified into Regular type and Fast type, depending on curing time, but there is no difference on viscosity, indications for use, or scope of use. Each device is consisted of 1:1 base and catalyst component, packaged in 560mL jars for DENU Putty set and 50mL syringes for other devices.	Vonflex S™, as the additional polymerization silicone type, is composed of a two component (base and catalyst, mixing ratio 1:1) hydrophilic vinyl polysiloxane impression material for all dental impression techniques. Vonflex S™ consists of light-bodied, medium-bodied or heavy-bodied consistencies in delivery systems of cartridges and/or tubes. It has normal set and fast set that would be desired by the operator.	Same
Indications for use	• Crown and bridge impression • Inlay and onlay impression • Denture impression • Model impression	• Impression material in dual phase impression technique • Precise duplication of models • Capturing multiple unit impressions • Impression of inlay, crown, bridge and partial denture etc.	Same The subject and predicate device have the same intended use. Both devices are used for dental impression techniques according to their consistencies.
Physical State	Two product lines (DENU Light Body, DENU heavy Body) are provided with	Various pastes with various viscosity	Similar Both subject and predicate devices are

		different viscosity.		provided as putties with various elasticities. The physical states are similar, as compared in physical properties.
Structure		Addition type silicone based elastomeric impression materials	Addition type silicone based elastomeric impression materials	Same
Packaging		Primary packaging : Cartridges Secondary packaging : Fiberboard	Primary packaging : Cartridges Secondary packaging : Fiberboard	Same
Usage		Single patient, single use. Not reusable	Single patient, single use. Not reusable	Same
Sterility		Non-sterile	Non-sterile	Same
Handling System		Two part base/catalyst system	Two part base/catalyst system	Same
Type of Curing		Self-curing after mixing of base and catalyst part.	Self-curing after mixing of base and catalyst part.	Same
Physical properties	Light body, regular	See the table below	See the table below	Similar Individual values of physical properties are same or similar. Every physical property of predicate and subject device conforms to the related standard.
	Light body, fast	See the table below	See the table below	
	Heavy body, regular	See the table below	See the table below	
	Heavy body, fast	See the table below	See the table below	
Chemical composition		Vinyl siloxanes Vinyl terminated cyclosiloxanes	Vinyl siloxanes	Similar Both device are composed of vinyl terminated siloxane, cross-linking siloxane, Filler,
		Siloxane and Silicone, di-Me, Me Hydrogen	Hydrogen polysiloxane	
		Silica	Silica	

	Silicon dioxide	Fumed silica	platinum catalyst, pigments and surfactant.
	Pt-divinyltetramethyldisiloxane in Polysiloxane	Organo platinum complex	
	Pigments	Pigments	
	surfactant	Surfactant	
Biocompatibility	Meets ISO 10993-1 for a surface device contacting mucosal membrane and dentin for a short-term contact duration (>24h)	Conforms with ISO 10993-1	Same
Standards conformed	ISO 4823 ISO 10993-1	ISO 4823 ISO 10993-1	Same

	DENU Light Body(Regular, Fast) DENU Heavy Body(Regular, Fast)		Vonflex STM	Standard	Discuss/Justify the Differences
	Subject device		Predicate device		
Working time	Light body, regular	1'30''	2'30''	[ISO 4823:2021 7.3] suggested value of the manufacturer	Equivalent
	Light body, fast	1'30''	1'30''		Equivalent
	Heavy body, regular	1'30''	2'15''		Equivalent
	Heavy body, fast	1'30''	1'30''		Equivalent
Setting reaction time	Light body, regular	4'10''	4'00''	[ISO 4823:2021 7.3] suggested value of the manufacturer	Equivalent
	Light body, fast	2'40''	2'30''		Equivalent
	Heavy body, regular	4'10''	4'00''		Equivalent
	Heavy body, fast	2'40"	2'30''		Equivalent
Consistency	Light body, regular	39.18 ㎜	43.43 ㎜	[ISO 4823:2021 7.2] >= 36 mm	Equivalent
	Light body, fast	36.16 ㎜	42.02 ㎜		Equivalent
	Heavy body, regular	34.10 ㎜	34.76 ㎜	[ISO 4823:2021 7.2] < 35 mm.	Equivalent
	Heavy body, fast	32.54 ㎜	34.78 ㎜		Equivalent
Compatibility with gypsum	Light body, regular	Reproduced for 0.05 ㎜	Reproduced for 0.05 ㎜	[ISO 4823:2021 7.6] 50 μm should be	Equivalent
	Light body, fast	Reproduced	Reproduced		Equivalent

		for 0.05 ㎜	for 0.05 ㎜	reproduced without interruption.	
	Heavy body, regular	Reproduced for 0.05 ㎜	Reproduced for 0.05 ㎜		Equivalent
	Heavy body, fast	Reproduced for 0.05 ㎜	Reproduced for 0.05 ㎜		Equivalent
Strain in compression (Curve of the shrinkage)	Light body, regular	2.52%	7.71%	[ISO 4823: 2021 7.8] it should be within 2.0~20 %	Similar Both conforms to the standard
	Light body, fast	2.58%	5.24%		Similar Both conforms to the standard
	Heavy body, regular	1.54%	2.56%	[ISO 4823: 2021 7.8] within 0.8~20 %	Similar Both conforms to the standard
	Heavy body, fast	1.10%	2.38%		Similar Both conforms to the standard
Dimensional accuracy	Light body, regular	0.09%	0.08%	[ISO 4823:2021 7.5] <= 1.5 %	Equivalent
	Light body, fast	0.13%	0.09%		Similar Both conforms to the standard
	Heavy body, regular	0.20%	0.11%		Similar Both conforms to the standard
	Heavy body, fast	0.27%	0.07%		Similar Both conforms to the standard

510(k) Summary of Vonflex STM is provided in Appendix D_K152615 Vonflex S, Vericom

	Subject device	Predicate Device	Discuss/Justify the Differences
510(k) Number	New	K152518	-
Trade Name	DENU Putty Set(Regular, Fast)	Vonflex S Putty	-

Manufacturer	HDI, Inc.	Vericom Co. Ltd	-
Common Name	Impression material	Impression material	Same
Device Class	2	2	Same
Product Code	ELW	ELW	Same
Device Description	The DENU family of silicone impression materials consists of three different viscosities (light body, heavy body, putty) for various application systems. Products are further classified into Regular type and Fast type, depending on curing time, but there is no difference on viscosity, indications for use, or scope of use. Each device is consisted of 1:1 base and catalyst component, packaged in 560mL jars for DENU Putty set and 50mL syringes for other devices.	Vonflex STM Putty, as the additional polymerization silicone type, is composed of vinyl polysiloxane impression materials that make oral tissue shape precisely. Vonflex STM Putty is very easy to mix and has good dimensional stability, helps to make precise impression taking.	Same
Indications for use	• Crown and bridge impression • Inlay and onlay impression	It is used for all crown, bridge and orthodontic impression techniques.	Same The subject and predicate device have the same intended use. Inlay/onlay are smaller cavity rather than a crown limited to one tooth, therefore it can also be used for inlay/onlay if it is possible to obtain a crown impression.
Physical State	Various putties with various	Viscous pastes with various	Similar

		elasticities. DENU Putty Set (Fast, Regular) are provided with different elasticity.	viscosity and putties with various elasticities	Both subject and predicate devices are provided as putties with various elasticities. The physical states are similar, as compared in physical properties.
Structure		Addition type silicone based elastomeric impression materials	Addition type silicone based elastomeric impression materials	Same
Packaging		Primary packaging : Jar Secondary packaging : carton box	Primary packaging : Jar Secondary packaging : carton box	Same
Usage		Single patient, single use. Not reusable	Single patient, single use. Not reusable	Same
Sterility		Non-sterile	Non-sterile	Same
Handling System		Two part base/catalyst system	Two part base/catalyst system	Same
Type of Curing		Self-curing after Hand-kneaded mixes	Self-curing after Hand-kneaded mixes	Same
Physical properties	DENU Putty Set Regular	See the table below	See the table below	Same The classification of the subject and predicate device is complied with ISO 4823 (Type 0).
	DENU Putty Set Fast	See the table below	See the table below	
Chemical composition		Vinyl siloxanes Vinyl terminated	Vinyl siloxanes	Similar Both device are

	cyclosiloxanes		composed of vinyl terminated siloxane, cross-linking siloxane, Filler, platinum catalyst, pigments and surfactant.
	Talc Diatomite Silica Silicon dioxide	Silica Fumed silica	
	Siloxane and Silicone, di-Me,Me Hydrogen	Hydrogen polysiloxane	
	Pt-divinyltetramethyldisiloxane in Polysiloxane	Organo platinum complex	
	Pigments	Pigments	
		Surfactant	
Biocompatibility	Meets ISO 10993-1 for a surface device contacting mucosal membrane and dentin for a short-term contact duration (>24h)	Conforms with ISO 10993-1	Same
Standards conformed	ISO 4823 ISO 10993-1	ISO 4823 ISO 10993-1	Same

	DENU Putty Set Regular		Vonflex STM	Standard	Discuss/Justify the Differences
	DENU Putty Set Fast				
	Subject device		Predicate device		
Dimensional accuracy	Putty Set Regular	0.21%	<=1.5 %	[ISO 4823:2021 7.5] <=1.5 %	Similar Both conforms to the standard
	Putty Set Fast	0.17%	<=1.5 %		Similar Both conforms to the standard
Consistency	Putty Set Regular	26.72 mm	43.43 ㎜	[ISO 4823:2021 7.2] < 35 mm	Equivalent
	Putty Set Fast	27.94 mm	< 35 mm		Equivalent

Compatibility with gypsum	Putty Set Regular	Reproduced for 75µm	75 µm reproduction	[ISO 4823:2021 7.6] 75 µm should be reproduced	Equivalent
	Putty Set Fast	Reproduced for 75µm	75 µm reproduction		Equivalent
Strain in compression(Curve of the shrinkage)	Putty Set Regular	1.74%	0.8~20 %	[ISO 4823:2021 7.8] 0.8~20 %	Similar Both conforms to the standard
	Putty Set Fast	1.60%	0.8~20 %		Similar Both conforms to the standard
Working time	Putty Set Regular	1'30''	more than or equal to the suggested value of the manufacturer	[ISO 4823:2021 7.3] more than or equal to the suggested value of the manufacturer	Similar Both conforms to the standard
	Putty Set Fast	1'30''	more than or equal to the suggested value of the manufacturer		Similar Both conforms to the standard
mixing time	Putty Set Regular	26.2"	<= 60 sec	[ISO 4823:2021 7.1] <= 60 sec	Similar Both conforms to the standard
	Putty Set Fast	21.4"	<= 60 sec		Similar Both conforms to the standard

510(k) Summary of Vonflex S Putty is provided in Appendix E_K152518 Vonflex S Putty, Vericom

8. SUBSTANTIAL EQUIVALENCE DISCUSSION

Subject devices have the same Indications for Use and the principle of operations as the predicate devices. They are intended to perform as impression material which met the requirement according to ISO 4823. They demonstrate similar physical properties and biocompatibilities with comparable performance specifications to the predicate devices.

In terms of physical equivalence, information about working time, setting reaction time, consistency, compatibility with gypsum, strain in compression, dimensional accuracy,

flow properties, tear strength, viscosity, wettability is measured by performance test or retrieved from manufacturer. Among those physical properties, values present on both predicate device and subject device, or values specified by ISO 4823 are compared to show equivalence, better performance, or conformation to the related standard on each endpoint.

In terms of clinical equivalence, both subject and predicate device are classified under the same product code(ELW), and have equivalent indication of use (crown, bridge, and other orthodontic impression).

In terms of chemical equivalence, chemical constituents of both devices are analyzed and classified into comparable molecular subgroup. Even though the exact material does not necessarily coincide on each subgroup, essential composition of the subgroup is the same; vinyl terminated siloxane, cross-linking siloxane, Filler, platinum catalyst, pigments, and surfactant.

In terms of biological equivalence, the bench and biocompatibility testing performed demonstrates that any differences in their technological characteristics do not raise any new questions as to safety and effectiveness. Therefore, it is concluded that subject devices are substantially equivalent to the predicate devices.