February 13, 2024

B&E Korea Co., Ltd.
Jayong Shin
RA Representative
995-16, Baran-ro, Jeongnam-myeon
Hwaseong-si, Gyeonggi-do 18515
SOUTH KOREA

Re: K233954
Trade/Device Name: Chemi-SiL (HB, MB, LB, LBS) and Chemi-SiL Bite-Blu
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: December 15, 2023
Received: December 15, 2023

Dear Jayong Shin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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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: 07/31/2026
See *PRA Statement below.*

Submission Number *(if known)*

K233954

Device Name

Chemi-SiL (HB, MB, LB, LBS)
Chemi-SiL Bite-Blu

Indications for Use *(Describe)*

Chemi-SiL (HB, MB, LB, LBS)
- Crown and bridge impression, inlay and onlay impressions

Chemi-SiL Bite-Blu
- Impression of the occlusal surface

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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K233954

510(k) SUMMARY

Date: Dec 15, 2023

1. SUBMITTER

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2. DEVICE

·Trade Name: Chemi-SiL (HB, MB, LB, LBS), Chemi-SiL Bite-Blu

·Common Name: Impression Material

·Classification Name: Material, Impression

·Regulation Number: 872.3660

·Class: 2

·Classification Product Code: ELW

3. PREDICATE DEVICE

Chemi-SiL (HB, MB, LB, LBS)

K152615 Vonflex S™, Vericom Co. Ltd

Chemi-SiL Bite-Blu

K170736 Hysil Impression Materials HySil Bite, OSSTEM Implant Co., Ltd.

4. DEVICE DESCRIPTION

Chemi-SiL of silicone impression materials are hydrophilic impression materials based on polyvinylsiloxane and it is used for impression of teeth or gingiva. It consists of three different consistencies (heavy body, light body, bite registration material) according to ISO 4823. And it is supplied base and catalyst in contrasting color.
Each product is consisted of 1:1 base and catalyst component, packaged in two 50 mL catridges.

5. INDICATIONS FOR USE

Chemi-SiL (HB, MB, LB, LBS)

- Crown and bridge impression, inlay and onlay impressions

Chemi-SiL Bite-Blu

- Impression of the occlusal surface

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	Chemi-SiL (HB, MB, LB, LBS)	Vonflex S™	-
Manufacturer	B&E KOREA Co., Ltd.	Vericom Co. Ltd	-
Common Name	Impression material	Impression material	Same
Device Class	2	2	Same
Product Code	ELW	ELW	Same
Indications for use	• Crown and bridge impression, inlay and onlay impressions	• 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 are provided with different viscosity. (Heavy body, Light body)	Various pastes with various viscosity	Similar 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: Cartridges Secondary packaging: Carton box	Primary packaging: Cartridges 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 mixing of base and catalyst part.	Self-curing after mixing of base and catalyst part.	Same
Physical properties	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.
Chemical composition	Poly(dimethylsiloxane), vinyl terminated	Vinyl siloxanes	Similar Both device are composed of vinyl terminated siloxane, cross-linking siloxane, Filler, platinum catalyst, pigments and surfactant.
	Siloxanes and Silicones, di-ME, ME Hydrogen, Hydrogen-terminated Methyl hydrogen polysiloxanes	Hydrogen polysiloxane	
	Synthetic amorphous Silica Hydrophilic Fumed Silica	Silica Fumed silica	
	Platinum complex (3 % Pt by weight)	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

Physical properties

-	Chemi-SiL (HB, MB, LB, LBS)	Vonflex STM	Standard	Discuss/Justify the

					Differences
Working time	MB	90 s	2′15″(Heavy, normal) 1′30″(Heavy, Fast)	[ISO 4823:2021 7.3] suggested value of the manufacturer	Equivalent
	HB				
	LB	90 s	2′30″(Light, normal) 1′30″(Light, Fast)		Equivalent
	LBS				
Setting reaction time	MB	210 s	4′00″ (Heavy, normal) 2′30″ (Heavy, Fast)	-	Equivalent
	HB				
	LB	210 s	4′00″(Light, normal) 2′30″(Light, Fast)		Equivalent
	LBS				
Consistency	MB	32.75 mm	34.76 mm (Heavy, normal) 34.78 mm (Heavy, Fast)	[ISO 4823:2021 7.2] <= 35 mm	Equivalent
	HB				
	LB	48.83 mm	43.43 mm (Light, normal) 42.02 mm (Light, Fast)	[ISO 4823:2021 7.2] > =36 mm	Equivalent
	LBS				
Compatibility with gypsum	MB	Reproduced for 0.05 mm	Reproduced for 0.05 mm	[ISO 4823:2021 7.6] 50 µm should be reproduced without interruption.	Equivalent
	HB				
	LB	Reproduced for 0.05 mm	Reproduced for 0.05 mm		Equivalent
	LBS				

Strain in compression (Curve of the shrinkage)	MB HB	1.2 %	2.56 % (Heavy, normal) 2.38 % (Heavy, Fast)	[ISO 4823: 2021 7.8] it should be within 0.8~20 %	Similar Both conforms to the standard
	LB LBS	3.1 %	7.71 % (Light, normal) 5.24 % (Light, Fast)	[ISO 4823: 2021 7.8] within 2.0~20 %	Similar Both conforms to the standard
Linear Dimensional Change	MB HB	0.12 %	0.11 % (Heavy, normal) 0.07 % (Heavy, Fast)	[ISO 4823:2021 7.5] <= 1.5 %	Similar Both conforms to the standard
	LB LBS	0.04 %	0.08 % (Light, normal) 0.09 % (Light, Fast)		Similar Both conforms to the standard

510(k) Summary of Vonflex S^{TM} is provided in Appendix A_K152615

	Subject device	Predicate Device	Discuss/Justify the Differences
510(k) Number	New	K170736	-
Trade Name	Chemi-SiL Bite-Blu	Hysil Impression Materials HySil Bite	-
Manufacturer	B&E KOREA Co., Ltd.	OSSTEM Implant Co., Ltd.	-
Common Name	Impression material	Impression material	Same
Device Class	2	2	Same
Product Code	ELW	ELW	Same
Indications for use	• Impression of the occlusal surface	HySil Bite is used for impression as below. - Taking occlusal surfaces - Confirming occlusal surfaces - Recording after putting the	Same

			articulator	
Physical State		Bite registration materials	Bite registration materials	Same
Structure		Addition type silicone based elastomeric impression materials	Addition type silicone based elastomeric impression materials	Same
Packaging		Primary packaging: Cartridge Secondary packaging: Carton box	Primary packaging: Cartridge 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	Colours	Pass	Pass	Same The classification of the subject and predicate device is complied with DIN 13903
	Working time	55 s	Pass	
	Minimum period spent in the mouth	95 s	1 min. 30 sec	
	Recovery after Deformation	0.0 mm	more than 0.1 mm	
	Load endurance during bending(Flexural strength)	8.2 N(20 s)	Pass	
	Hardness degree(HD)	50 HD	50 HD	
	Linear dimensional change	0.3 %	-0.16 %	

Chemical composition	Poly(dimethylsiloxane), vinyl terminated	Vinylpolysiloxane	Similar Both device are composed of vinyl terminated siloxane, Filler, platinum catalyst and pigment.
	Hydrophilic fumed Silica Synthetic amorphous Silica		
	Pigment		
	Platinum complex		
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	DIN 13903 ISO 10993-1	DIN 13903 ISO 10993-1	Same

510(k) Summary of Hysil Impression Materials HySil Bite is provided in Appendix B_K170736

8. CONCLUSION

Subject devices have the same intended use and the principle of operation as the predicate devices. They are intended to perform as impression materials which meet the requirements according to ISO 4823. Both subject and predicate devices are classified under the same product code (ELW) and have equivalent indications of use (crown and bridge impressions, inlay and onlay impressions for Chemi-SiL (HB, MB, LB, LBS), and impression of the occlusal surface for Chemi-SiL Bite-Blu).

Both devices demonstrate similar physical properties and biocompatibilities with comparable performance specifications to the predicate devices. Information about working time, setting reaction time, consistency, compatibility with gypsum, strain in compression, and linear dimensional change is compared between Chemi-SiL (HB, MB, LB, LBS) and Vonflex S^{TM}. Colour, working time, minimum period spent in the mouth, recovery after deformation, load endurance (flexural strength), hardness degree (HD), and linear dimensional change are compared between Chemi-SiL Bite-Blu and Hysil Impression Materials HySil Bite. All subject

devices have shown better or equivalent performance compared to the predicate device, or have shown compliance with the device-specific standard (ISO 4823) at each endpoint.

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

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