DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Osstem Implant Co., Ltd.. June 7, 2017
% David Kim
Manager
HiOSSEN Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K170736
Trade/Device Name: HySil Impression Materials
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: March 1, 2016
Received: March 28, 2017

Dear David 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -A

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

OSSTEM Implant Co., Ltd.
66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Republic of Korea
Tel: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

510(k) Number K k170736

Device Name : HySil Impression Materials

Indication for use :

HySil Putty is to be used as preliminary materials for:
- Two-step Putty-wash impression technique
- One-step Putty-wash impression technique

HySil Heavy is to be used as heavy-bodied materials for:
- One-step impression technique (simultaneous technique) using single or dual viscosities
- Two-step impression technique using dual viscosities
- Functional impressions

HySil Mono is to be used as a medium-bodied tray or syringeable impression material for:
- Taking impressions over fixed/removable restorations and implants (i.e., transferring impression posts and bridge components)
- 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 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

HySil Extra Light 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

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HySil Bite is used for impression as below.

- Taking occlusal surfaces
- Confirming occlusal surfaces
- Recording after putting the articulator

Prescription Use___X____ OR Over-The-Counter Use _____.
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Republic of Korea
Tel: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

510(k) Summary

Date: March 27, 2017

1. Company and Correspondent making the submission:

- Submitter's Name:	Osstem Implant Co., Ltd.
- Address	# 66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Republic of Korea
- Contact:	Mr. Heekwon Son
- Phone:	+82 51 850-2575
- Correspondent's Name:	HIOSSEN Inc.
- Address:	85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact:	DAVID KIM
- Phone:	267 759 7031

2. Device:

Trade or (Proprietary) Name :	HySil Impression Materials
Common or usual name :	Impression material
Classification Name :	Material, Impression(21 CFR 872.3660)
Regulation Number :	21CFR872.3660
Device Classification:	Class II
Subsequent Product Code:	ELW

3. Predicate Device:

Primary Predicate
K133527, Suflex Impression Meterials to include: (Suflex putty, Suflex Heavy, Suflex Mono, Suflex Light), Osstem Germany GmbH.

Reference predicate
K151262, Hyflex Impression Materials including to include: (Hyflex Heavy, Hyflex Mono, Hyflex Light), Osstem Implant Co., Ltd.
K152766, CharmFlex®, Dentkist, Inc

4. Description
HySil Impression Materials are addition-curing, elastomeric materials with hydrophilic properties, high tear strength, dimensional accuracy, and resistance to permanent deformation. The HySil impression materials family consists of six different viscosities (putty, heavy, mono, light. Extra-light and Bite) available in an assortment of delivery systems: standard 1:1 50 ml automix cartridges, and traditional 1:1 putty jars.

Putty, Heavy, Mono, Light and Extra-light of this proposed devices are classified into Type 0, Type 1, Type 2, and Type 3 according to ISO 4823, and Bite is classified as Dentistry - Jaw relation recording material according to DIN 13903
HySil Bite is an addition-curing silicone bite registration materials in a 50ml cartridge type to measure accurate bite.
HySil Bite is suitable for bite registration as it has a short setting time, high final hardness after curing for user convenience, and less elastic deformation when eliminated.

Substantial Equivalence Chart

- Heavy, Mono, and Light

The predicate devices, Hyflex Heavy, Mono, and Light (K151262) are re-submitted to change their name as Hysil Heavy, Mono, and Light. There are no changes in composition, indications for use, technological characteristics, biocompatibilities, etc. They have difference in name only.

- Putty, Extra-Light

	Subject device	**Predicate device**	**Remark**
Descriptive Information	**HySil Impression material** Putty, Extra-Light	**Suflex Impression material** Putty, Light	
Company	Osstem Implant Co., Ltd.	Osstem Germany GmbH	
510(k) No.	Proposed	K133527	
Indication for Use	HySil Putty is to be used as preliminary materials for: • Two-step Putty-wash impression technique • One-step Putty-wash impression technique HySil Heavy is to be used as heavy-bodied materials for: • One-step impression technique (simultaneous technique) using single or dual viscosities • Two-step impression technique using dual viscosities • Functional impressions HySil Mono is to be used as a medium-bodied tray or syringeable impression material for:	*Suflex Putty is to be used as panasil putty material for; -Two step putty impression technique -One step putty impression technique -Two step putty impression technique using a foil(plastic putty spacer) -One step putty impression technique for forming functional peripheries. *Suflex Heavy is to be used a s panasil tray material for; -One step impression technique using single or dual viscosities. -Two step impression technique using dual viscosities -Functional impressions. *Suflex Mono is to be used as	The subject device and primary predicate have slightly different Indications for Use language. However, the difference in language does not change the intended use or substantial equivalence.

	• Taking impressions over fixed/removable restorations and implants (i.e., transferring impression posts and bridge components) • 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 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 HySil Extra Light 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 HySil Bite is used for impression as below. • Taking occlusal surfaces	panasil monophase material for; -Taking impression over fixed/removable restorations and implants(transferring impression posts and bridge components) -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 -Transferring root posts when fabricating posts and cores indirectly. *Suflex Light is to be used as panasil contact material for; -Two step putty impression technique. -One step putty impression technique. -One step impression technique using a foil(plastic putty spacer) -One step impression technique (simultaneous technique) using dual viscosities. - Reline impressions. - Fabricating full or partial dentures.	

	• Confirming occlusal surfaces • Recording after putting the articulator		
Description of Material	Vinylpolysiloxane	Vinylpolysiloxane	Composed with same affiliated material, but ratios of each component in use are slightly different.
Standard Conformed	ISO4823	ISO4823	Identical
Intended Use	- 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.	Identical
SE	**Similarities:** The subject devices and the predicate devices have same indications for use and intended use. They are all conformed to the ISO 4823 standard; also, both products are composed with same affiliated material called Vinylpolysiloxane. Therefore, the results of the performance testing and their composition are substantially equivalent. **Differences:** The ratios of each component or kinds of pigments of the materials in use are slightly different. However, based on the results of the performance and the biocompatibility testing, the subject and the predicate devices pass the requirements. ∴ Therefore, we state that HySil Impression Material is substantially equivalent to the predicate devices, Suflex Impression Material (K133527).		

- Bite

	Subject device	Predicate device	
Descriptive Information	**HySil Impression material <Bite>**	**CharmFlex CharmFlex® Bite Fast**	
Company	**Osstem Implant Co., Ltd.**	**Dentkist, Inc**	
510(k) No.	Proposed	K152766	
Description (Indication for use)	HySil Bite is used for impression as below. - Taking occlusal surfaces - Confirming occlusal surfaces - Recording after putting the articulator	CharmFlex®Bite series are bite registration impression material to measure of the occlusal surface, impression of the teeth for a three-dimension position of the mandible in relation to the maxilla. It has a short polymerization time and a high final hardness. Making it suitable for bite registration.	The subject device and predicate have slightly different Indications for Use description) language. However, the difference in language does not change the intended use or substantial equivalence.
Description of Material	Vinylpolysiloxane	Vinylpolysiloxane	Composed with same affiliated material, but ratios of each component in use are slightly different.
Standard Conformed	DIN 13903	CharmFlex® Bite Fast is tested according to DIN 13903	Identical
SE	**Similarities:** According to comparison test between the subject device and the predicate device, both of them are conformed to DIN 13903 standard; also, both products are composed with same affiliated material called Vinylpolysiloxane. Therefore, the results of the performance testing and their composition are substantially equivalent. **Differences:** The ratios of each component of the materials in use are slightly different. However, based on the results of the performance and the biocompatibility testing, the subject and the predicate devices pass the requirements.		

	∴ Therefore, we state that HySil Impression material, Bite is substantially equivalent to the predicate devices, CharmFlex® Bite Fast (K152766).

5. Intended use
- 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.

6. Indication for use

HySil Putty is to be used as preliminary materials for:
- Two-step Putty-wash impression technique
- One-step Putty-wash impression technique

HySil Heavy is to be used as heavy-bodied materials for:
- One-step impression technique (simultaneous technique) using single or dual viscosities
- Two-step impression technique using dual viscosities
- Functional impressions

HySil Mono is to be used as a medium-bodied tray or syringeable impression material for:
- Taking impressions over fixed/removable restorations and implants (i.e., transferring impression posts and bridge components)
- 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 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

HySil Extra Light 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

HySil Bite is used for impression as below.

- Taking occlusal surfaces
- Confirming occlusal surfaces
- Recording after putting the articulator

7. Summary of Non-Clinical Performance Testing

Biocompatibility tests have been performed to assure biological safety in accordance with the ISO 10993 family. Tests in respect to cytotoxicity (ISO 10993-5), sensitization and mucosa irritation (ISO 10993-10)

Additionally bench testing was performed to allow an evaluation of the mechanical properties of HySil in comparison to already marketed products according to ISO 4823.

- Visual, Weight(Volume) test, Package, Component Colour, Consistency, Detail Reproduction, Compatibility with Gypsum, Linear Dimensional change, Elastic Recovery, Strain-in-Compression

HySil Bite is classified as Dentistry - Jaw relation recording material according to DIN 13903
Therefore bench testing (mechanical properties) of HySil Bite was performed according to DIN 13903

- Visual(Colours), Working Time, Minimum Period Spent in the Mouth, Recovery after Deformation, Load Endurance during Bending, Hardness Degree(HD) and Linear Dimensional Change

< Comparison of physical properties and biological result >

HySil Extra Light and HySil Putty <according to ISO 4823 and ISO 10993 family>

	Subject device		**Predicate device**	
	Hysil Impression Meterials		Suflex Impression Meterials <K133527>	
	Extra Light	Putty	Light	Putty
Type	Type 3	Type 0	Type 3	Type 0
Component Colour	Pass	Pass	Pass	Pass
Weight(Volume) test	Pass	Pass	Pass	Pass
Package	Pass	Pass	Pass	Pass
Consistency	44.61mm	31.27mm	45.03mm	26.86 ㎜
Working Time	3.6min	-	2.25min	-
Mixing Time	-	38 sec	-	25 sec.
Detail Reproduction	Pass	Pass	Pass	Pass
Compatibility with Gypsum	Pass	Pass	Pass	Pass
Linear Dimensional change	0.027%	0.031%	0.04%	0.04%
Elastic Recovery	99.5%	99.8%	98.33%	97.78 %
Strain-in-Compression	2.6%	1.6%	3.87%	4.70 %
Report of test for cytotoxicity	Pass	Pass	Pass	Pass
Report of test for oral irritation	Pass	Pass	Pass	Pass
Report of test for maximization and sensitization	Pass	Pass	Pass	Pass

HySil Bite <according to DIN 13903 and ISO 10993 family>

	Subject device	**Predicate device**
	Hysil Impression Meterials HySil Bite	CharmFlex® Bite < K152766>
Colours	Pass	Pass
Working Time	Pass	Pass

(Processing Time)		
Minimum Period Spent in the Mouth	1 min. 30 sec	1 min. 30 sec
Recovery after Deformation	more than 0.1mm	more than 0.1mm
Load Endurance during Bending (Flexural strength)	Pass	Pass
Hardness Degree(HD) More than 20 HD	50 HD	74 HD, 72 HD, 70 HD, 64 HD and 70 HD
Linear Dimensional Change <shall be within ± 1.5 %.	- 0.16 %	0.00%, 0.00%, 0.10%, 0.10%, 0.02%
Report of test for cytotoxicity	Pass	Pass
Report of test for oral irritation	Pass	Pass
Report of test for maximization and sensitization	Pass	Pass

8. Summary of clinical testing
   No clinical studies are submitted

9. Conclusions
   Comparison results demonstrate that the specifications and performance of the device are same as the legally marketed predicate device.
   Therefore, Osstem Implant Co., Ltd. believes that the HySil Impression material is substantially equivalent to the currently legally marketed products.