Osstem Implant Co., Ltd.
% David Kim
Manager
Hiossen Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

September 13, 2018

Re: K181236
Trade/Device Name: HySil Impression Materials (Heavy, Mono, and Bite)
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: June 26, 2018
Received: June 26, 2018

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. 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 -S

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

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 181236

Device Name: HySil Impression Materials

Indication for Use:

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 Bite is used for impression as below.
- Taking occlusal surfaces
- Confirming occlusal surfaces
- Recording after putting the articulator

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

510(k) Summary K181236

Date: April 27, 2018

1. Company and Correspondent making the submission

- Submitter's Name	:	OSSTEM IMPLANT Co., Ltd.
- Address	:	66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, 612-070, Republic of Korea
- Contact	:	Ms. Jungmin Yoo
- Phone	:	+82-51-850-2575
- Correspondent's Name	:	HIOSSEN Inc.
- Address	:	85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact	:	Mr. David Kim
- Phone	:	267-759-7031

2. Device

- Trade or (Proprietary) Name	:	HySil Impression Materials
- Classification Name	:	Impression Material
- Regulation Number	:	21CFR872.3660
- Devce Classification	:	Class II
- Classification Product Code	:	ELW

3. Predicate Device

- Primary Predicate
  HySil Impression Materials, OSSTEM IMPLANT Co., Ltd. (K170736)

4. Description

HySil Impression materials are intended to 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.

HySil Heavy and HySil Mono are addition-curing, elastomeric materials with hydrophilic property, high tear strength, dimensional accuracy, and a high resistance to permanent deformation. HySil Heavy and HySil Mono are available in an assortment of delivery systems of traditional 1:1 50 ml automix cartridge (predicated, K170736) and 5:1 380 ml automix cartridge version for use in most automatic dispensing and mixing system. HySil Heavy and HySil Mono are classified into Type 1 and Type 2 according to ISO 4823 each.

HySil Bite is an addition-curing silicone bite registration materials in a 50 ml 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. HySil Bite is classified into jaw relation recording material according to DIN 13903.

5. Substantial Equivalence Matrixes

- HySil Heavy and HySil Mono (Addition in 5:1 380 ml automix cartridge version)

	Proposed Devices	Predicated Devices	Remark
510(k) No.	Proposed	K170736	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Same
Indications for Use	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 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	Same

Description of Material	Vinylpolysiloxane	Vinylpolysiloxane	Composed with same affiliated materials, but ratios of each component in use are slightly different
Standard Conformed	ISO 4823	ISO 4823	Same
Shelf Life	2 years	2 years	Same
S.E.	**Similarities:** The proposed devices and the predicated devices have same indications for use and have same shelf life of 2 years. 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:** Compared to the predicated devices, the proposed devices don't have L-menthol in their composition. 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 device passed the requirements. ∴ Therefore, we state that proposed devices (HySil Heavy and Mono, 5:1 380 ml automix cartridge) are substantially equivalent to the predicated devices (HySil Heavy and Mono, 1:1 50 ml automix cartridge) cleared in K170736.		

- HySil Bite (Change in guidance of working time only)

	Proposed Devices	Predicated Devices	Remark
510(k) No.	Proposed	K170736	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Same
Indications for Use	HySil Bite is used for impression as below. - Taking occlusal surfaces - Confirming occlusal surfaces - Recording after putting the articulator	HySil Bite is used for impression as below. - Taking occlusal surfaces - Confirming occlusal surfaces - Recording after putting the articulator	Same
Working Time	30 seconds or more	15 seconds or more	Different
Description of Material	Vinylpolysiloxane	Vinylpolysiloxane	Same
Standard Conformed	DIN 13903	DIN 13903	Same
Shelf Life	3 years	3 years	Same

S.E.	**Similarities:** The proposed device and the predicated device have same indications for use and have same shelf life of 3 years. They are all conformed to the DIN 13903 standard; also, both products are composed with same affiliated material called Vinylpolysiloxane. **Differences:** The working time (processing time) of device is guided by the manufacturer. The working time of the proposed device is 30 seconds or more while the predicated device is 15 seconds or more. Physical test for changing guidance of working time was conducted and it passed the criteria of DIN 13903 standard. ∴ Therefore, we state that propose device is substantially equivalent to the predicated device cleared in K170736.

6. Indication for Use

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 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

Non-clinical testing data are submitted, referenced, or relied upon to demonstrate substantial equivalence.

Biocompatibility evaluation

Biocompatibility tests including cytotoxicity, skin sensitization, oral mucosa irritation, and acute systemic injection have been performed to assure biological safety in accordance with ISO 10993-5, 10993-10, and 10993-11.

Sterilization Validation and Shelf-life

All subject devices in HySil Impression materials are delivered in non-sterile. Therefore, sterilization validation was not considered. For the shelf-life of subject devices, we conducted real-time shelf-life tests and leveraged the data that of our prior submissions.

Mechanical Properties

Bench tests evaluated for HySil Impression Materials included visual, weight, package, component color, consistency, detail reproduction, compatibility with gypsum, linear dimensional change, elastic recovery, strain-in-compression, and working time in accordance with ISO 4823 and DIN 13903. Mechanical properties from bench tests of HySil Impression Materials found substantially equivalent to the predicate devices.

8. Summary of Clinical Testing

No clinical studies are submitted.

9. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, OSSTEM IMPLANT Co., Ltd. concludes that the HySil Impression Materials are substantially equivalent to the predicated devices as herein.