March 18, 2021

Osstem Implant Co., Ltd.
% Peter Lee
QA/RA Manager
Hiossen Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K210041
Trade/Device Name: HySil Plus Impression Materials
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: January 19, 2021
Received: January 21, 2021

Dear Peter Lee:

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, M.ChE.
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Osstem Implant Co., Ltd.
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510(k) Number: K210041

Device Name: HySil Plus Impression Materials

Indications for Use:

HySil Heavy Plus 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 Plus 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 impressi on 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 Plus 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 Heavy Plus Auto 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

[X] Prescription Use (21 CFR 801 Subpart D) [ ] Over-The Counter Use (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

Date: December 30, 2020

1. Company and Correspondent making the submission

- Submitter's Name : Osstem Implant Co., Ltd.
- Address : 66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, 48002, Republic of Korea
- Contact : Mr. Jinwoo Bae
- Phone : +82-51-850-2500

- Correspondent's Name : Hiossen Inc.
- Address : 85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact : Mr. Peter Lee
- Phone : +1-267-759-7031

2. Proposed Device

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

3. Predicated Device

- Primary Predicate
  HySil Super Fast Impression Materials, Osstem Implant Co., Ltd. (K192941)
  HySil Heavy Plus Impression Materials, Osstem Implant Co., Ltd. (K181236)

4. Description

HySil Heavy Plus, HySil Mono Plus, HySil Light Plus, HySil Heavy Plus Auto (hereinafter referred to as the"HySil Plus Impression Materials") meet ISO 4823 standard and consist of three different viscosities (heavy-bodied, medium-bodied, and light-bodied) in delivery system as standard 1:1 50ml cartridges automix cartridges, 5:1 380ml cartridges for use in most Auto-mix dispensing and mixing systems.

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5. Substantial Equivalence Matrix

1) HySil Heavy, Mono, Light Plus

	Proposed Devices	Predicated Devices	Remark
Device Name	**HySil Plus Impression Materials** Heavy, Mono, Light, Heavy Auto	**HySil Super Fast Impression Materials** Heavy, Mono, Light	Different
510(k) No.	K210041	K192941	Different
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Same
Indications for Use	**HySil Heavy Plus** 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 Plus** 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	**HySil Heavy Super Fast** 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 Super Fast** 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	Same

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	- 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 Plus** 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	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 Super Fast** 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	
Principle of Operation	- 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	Same

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Description of Material	Vinylpolysiloxane	Vinylpolysiloxane	Compose with same affiliated material, but ratios of each component in use are different
Standard Conformed	ISO 4823	ISO 4823	Same
Working Time	Over 2 min.	Over 1 min. 15 sec.	Proposed devices have longer working time
Shelf-life	2 years	2 years	Same
Compatible Accessories	Mixing Tip Oral Tip Dispenser Gun	Mixing Tip Oral Tip Dispenser Gun	Same
S.E.	**Similarities** The proposed devices and the predicated devices are made with same affiliated material called Vinylpolysiloxane conformed to ISO 4823 standard. HySil Heavy Plus/Mono Plus/Light Plus are delivered in 50 ml catridge with base and catalyst ratio of 1 to 1; have same indications for use; have same principle of operation; and have same shelf-life. **Differences** Compared to the predicated devices, the proposed devices have different composition ratio and working time proposed from manufacturer. However, the proposed and the predicated devices both meet the requirements in regard with performance and biocompatibility test according to the ISO4823. Thus, the differences in composition rations and delivered type do not affect the substantial equivalence of proposed devices since the proposed products meet ISO ➢ Therefore, we stated that proposed devices (HySil Heavy Plus, Mono Plus, Light Plus) are substantially equivalent to the predicated devices (HySil Heavy, Mono, Light Super Fast Impression Materials) cleared in K192941.		

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2) HySil Heavy Plus Auto

	Proposed Devices	Predicated Devices		Remark
Device Name	**HySil Plus Impression Materials** Heavy Plus Auto	**HySil Super Fast Impression Materials** Heavy	**HySil Impression Materials** Heavy	Different
510(k) No.	K210041	K192941	K181236	Different
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Same
Indications for Use	**HySil Heavy Plus Auto** 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 Heavy Super Fast** 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 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	Same
Principle of Operation	- 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	- 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	- 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	Same

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	and gums - Provide models for study and for production of restorative prosthetic devices	and gums - Provide models for study and for production of restorative prosthetic devices	and gums - Provide models for study and for production of restorative prosthetic devices	
Description of Material	Vinylpolysiloxane	Vinylpolysiloxane	Vinylpolysiloxane	Compose with same affiliated material, but ratios of each component in use are different
Standard Conformed	ISO 4823	ISO 4823	ISO 4823	Same
Working Time	Over 2 min.	Over 1 min. 15 sec.	Over 2 min.	Same/ Different
Shelf-life	2 years	2 years	2 years	Same
Compatible Accessories	Mixing Tip Auto Mixer	Mixing Tip Oral Tip Dispenser Gun	Mixing Tip Auto Mixer	Same/ Different
S.E.	**Similarities** The proposed devices and the predicated devices are made with same affiliated material called Vinylpolysiloxane conformed to ISO 4823 standard. In addition, the proposed product has same indication for use, principle of operation and shelf-life. **Differences** Compared to the predicated devices, the proposed devices(HySil Heavy Plus auto) have different composition ratios, working time proposed from manufacturer and delivered type that is bulk type(automix cartridge version). In case of automix cartridge version, it has been developed for user's convenience. Although, there are some differences such as composition ratios, working time and delivered type, the proposed and the predicated devices both meet the requirements in regard with performance and biocompatibility test according to the ISO4823. Thus, the differences in composition rations and delivered type do not			

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	affect the substantial equivalence of proposed device. ➢ Therefore, we stated that proposed device (Heavy Plus Auto) is substantially equivalent to the predicated devices (HySil Heavy Super Fast Impression Materials) cleared in K192941.

6. Indications for Use

HySil Heavy Plus 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 Plus 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 Plus 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

7. Summary of Non-clinical Performance Testing

Non-clinical testing data are submitted to demonstrate substantial equivalence.

Biocompatibility Evaluation
Biocompatibility testing was considered followed the FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,"* and the ISO 10993-5, 10 and 11 including cytotoxicity, skin sensitization, oral mucosa irritation, and acute systemic toxicity test.

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Sterilization Validation and Shelf-life

Proposed devices are delivered in non-sterile. Therefore, sterilization validation was not considered. The Shelf-life testing was considered followed the FDA Guidance Document *Shelf Life of Medical Device*, ISO 4823; and determined shelf-life of proposed devices are 2 years.

Mechanical Properties

Mechanical testing was evaluated following ISO 4823 including visual, weight, package, component color, consistency, detail reproduction, compatibility with gypsum, linear dimensional change, elastic recovery, strain-in-compression, and working time, and it was found that the proposed devices are substantially equivalent to the predicate devices from the result of bench test.

8. Summary of Clnical 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 Plus Impression Materials are substantially equivalent to the predicated devices as herein.