



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 21, 2015

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

Re: K151262

Trade/Device Name: Hyflex Heavy, Hyflex Mono, Hyflex Light
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: May 8, 2015
Received: May 13, 2015

Dear Patrick Lim:

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 yours,

A handwritten signature in black ink that reads "Susan R. Keith, DDS, MA". The signature is written in a cursive style. A faint, semi-transparent "FDA" logo is visible in the background behind the signature.

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number K _____

Device Name : Hyflex impression materials

Indication for use :

Hyflex Heavy and Mono are 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.

Hyflex Mono is to be used as a medium-bodied tray or syringeable impression material for;

- Taking impression 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.

Hyflex Light is to be used as syringeable impression materials for;

- Two step putty-wash impression technique.
- One step putty-wash impression technique.
- One step impression technique using a foil(plastic putty spacer).
- Reline impressions.
- Fabricating full or partial dentures.

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

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: May 8, 2015

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: | +51 850-2575 |
| - Correspondent's Name: | HIOSSSEN Inc. |
| - Address: | 85 Ben Fairless Dr. Fairless Hills, PA 19030 |
| - Contact: | Patrick Lim |
| - Phone: | 888 678 0001 |

2. Device :

- | | |
|-------------------------------|--|
| Trade or (Proprietary) Name : | Hyflex Impression Materials including to include:
Hyflex Heavy
Hyflex Mono
Hyflex Light |
| Common or usual name : | Impression material |
| Classification Name : | Material, Impression(21 CFR 872.3660)
21CFR872.3660
Class II
ELW |

3. Predicate Device:

Trade Name: Suflex Impression Materials to include:(Suflex putty, Suflex Heavy, Suflex Mono, Suflex Light) K133527

4. Description

Hyflex Impression Materials are addition-curing, elastomeric materials with hydrophilic properties, high tear strength, dimensional accuracy, and resistance to permanent deformation. The Hyflex Impression Material family consists of three different viscosities(heavy, mono, light)

5. Intended use

- The Hyflex impression materials are intended to be 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

Hyflex Heavy and Mono are 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.

Hyflex Mono is to be used as a medium-bodied tray or syringeable impression material for;

- Taking impression 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.

Hyflex Light is to be used as syringeable impression materials for;

- Two step putty-wash impression technique.
- One step putty-wash impression technique.
- One step impression technique using a foil(plastic putty spacer).
- Reline impressions.
- Fabricating full or partial dentures

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) and a chemical analysis showed, that Hyflex materials' biocompatibility data is comparable to other materials on the market.

Additionally bench testing was performed to allow an evaluation of the mechanical properties of Hyflex in comparison to already marketed products. The evaluation covers

- Component colours (ISO 4823, 6.1)
- Working time (ISO 4823, 6.3)
- Compatibility with gypsum (ISO 4823, 6.4)
- Consistency(ISO 4823, 6.4)
- Detail reproduction(ISO 4823, 6.4)
- Linear dimensional change(ISO 4823, 6.4)
- Elastic recovery(ISO 4823, 6.4)
- Strain-in-compression(ISO 4823, 6.4)

< Comparison of physical properties and biological result >

	Hyflex Impression Materials			Suflex Impression Materials K133527		
	Heavy	Mono	Light	Heavy	Mono	Light
Consistency	28.47mm	35.65mm	45.60mm	32.96mm	38.89mm	45.03mm
Working Time	2.022min	2.612min	2.850min	2.02min	1.53min	2.25min
Detail Reproduction	Pass	Pass	Pass	Pass	Pass	Pass
Compatibility with Gypsum	Pass	Pass	Pass	Pass	Pass	Pass
Linear Dimensional change	0.02%	0.02%	0.03%	0.04%	0.04%	0.04%
Elastic Recovery	98.80%	98.60%	98.70%	98.41%	98.77%	98.33%
Strain-in-Compression	2.30%	3.00%	2.30%	3.53%	4.35%	3.87%
Report of test for cytotoxicity	Pass	Pass	Pass	Pass	Pass	Pass
Report of test for oral irritation	Pass	Pass	Pass	Pass	Pass	Pass
Report of test for maximization and sensitization	Pass	Pass	Pass	Pass	Pass	Pass

8. Summary of clinical testing

No clinical studies are submitted

9. Conclusions

Osstem Implant Co., Ltd. believes that the Hyflex Impression material is substantially equivalent to the currently legally marketed products. It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or safety risks.