May 7, 2019

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

Re: K181854
Trade/Device Name: OssBuilder System
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: Class II
Product Code: DZL, NHA
Dated: April 4, 2019
Received: April 5, 2019

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/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,

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Number: K 181854

Device Name: OssBuilder System

Indication for Use:

The OssBuilder System is used for space maintenance and stabilization of bone grafting material in an alveolar bone defect site.

[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

K181854

Date: May 07, 2019

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	:	+82-51-850-2500
- Correspondent's Name	:	HIOSSEN Inc.
- Address	:	85 Ben Fairless Dr. Fairless Hills, PA, 19030
- Contact	:	PETER LEE
- Phone	:	267-759-7031

2. Device

- Trade or (Proprietary) Name	:	OssBuilder System
- Classification Name	:	Intraosseous Fixation Screw or Wire
- Regulation Number	:	21CFR872.4880
- Devce Classification	:	Class II
- Classification Product Code	:	DZL
- Subsequent Product Code	:	NHA

3. Predicate Device

- Primary Predicate
  Neo GBR System, Neobiotech Co., Ltd. (K160991)

- Reference Predicate
  OssBuilder System, OSSTEM Implant Co., Ltd. (K172354)

4. Description

OssBuilder System is consisted of metal devices, OssBuilder, Healing Cap, Cover Cap, OB Anchor, and Tenting Screw, and is intended for use to stabilize and support of bone graft in dento-alveolar bony defect sites.

Tenting Screw, a product in the OssBuilder System product group, is a temporary dental implant that can be implanted in the bone defect site of the alveolar bone to fix the guided tissue regeneration material.

Healing Cap is used by connecting with the Tenting Screw to bind OssBuilder during osseointegration.

Item	**Content**		
Tenting Screw	Description	Tenting Screw is used for space maintenance of the bone graft material for horizontal and vertical bone augmentation in the alveolar bone defect site.	
	Material	Ti-6Al-4V (ASTM F 136)	
	Dimension (mm)	D (Ø, implanted)	2.1
		Total Length	8.5, 10.0, 11.5, 13.0
Healing Cap	Description	Healing Cap is used by connecting with the Tenting Screw to bind OssBuilder during osseointegration.	
	Material	Ti-6Al-4V (ASTM F 136)	
	Dimension (mm)	D (Ø)	4, 5
		Total Length	7, 8

The OssBuilder System is compatible with OssBuilder, Healing Cap, and Cover Cap of OssBuilder System cleared in K172354.

5. Substantial Equivalence Matrixes

	OssBuilder System	**Neo GBR System**	**Remark**
510(K)	Proposed	Predicated (K160991)	-
Manufacturer	Osstem Implant Co., Ltd.	Neobiotech. Co., Ltd.	Different
Device Name	Tenting Screw	Tent Screw	Different
Design			Similar

Indication for Use	The OssBuilder System is used for space maintenance and stabilization of bone grafting material in an alveolar bone defect site.	Neo GBR System is intended to fixate and stabilize non-resorbable barrier membranes used for regeneration of tissue in the oral cavity or in dental situations that require membrane use or fixation.	The propose device and the predicated device has different indication for use in language. The indication for use for the proposed device is for individual device (Tenting Screw) within the system, while the indication for use for the predicated device is for the overall devices in the Neo GBR System. Therefore, it can be said that the indication for use for both devices are equivalent when viewed as a whole system.
Principle of Operation	Tenting Screw is placed in maxilla or mandible bone area to be combined with OssBuilder (non-resorbable titanium membrane) and Healing Cap or Cover Cap. It helps to support and prevent the mobility of the membrane during the bone regeneration. Since it is used for temporary use, second surgery is required to remove them after bone regeneration.	The function of Bone screw body is temporary dental implant (Screw) that place in maxilla or mandible bone area to be combined with titanium membrane and cover screw or cover cap. It helps to support the membrane. Second surgery for removal is required.	The proposed device and the predicated device has different principle of operation in language, however the difference in language does not change the intended use or substantial equivalence status.
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Identical
Head Diameter (mm)	3.0	2.85	Similar
Major Thread Diameter (mm)	2.1	2.0	Similar
Length (mm)	8.5, 10.0, 11.5, 13.0	7.2, 8.7, 10.2, 11.7, 13.2, 15.2, 18.2	Within the range of the predicated.
Sterilization	Gamma Sterilization	Gamma Sterilization	Identical
Shelf Life	8 years	Unknown	Similar

S.E.	**Similarities** The proposed Tenting Screw has similar shape, is made of same material and has same sterilization method compared to the predicated Tent Screw of Neo GBR System (K160991). **Differences** The implanted diameter and the length of the proposed device and the predicated device are different. ∴ While its dimension is different from the predicated, the proposed Tenting Screw is made of same material and has same function and intended use; therefore, the proposed Tenting Screw is substantially equivalent to the predicated Tent Screw of Neo GBR System (K160991).

	OssBuilder System	**OssBuilder System**		**Remark**
510(k) No.	Proposed	Predicated (K172354)		-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.		Identical
Device Name	Healing Cap	Healing Cap	Cover Cap	Identical
Design				Identical
Intended Use	OssBuilder System is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	OssBuilder System is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.		Identical
Principle of Operation	Where Tenting Screw is placed in maxilla or mandible bone area, it is combined with OssBuilder (non-resorbable titanium membrane) and Healing Cap or Cover Cap. Healing Cap is intended by connecting with Tenting Screw to fix OssBuilder during osseointegration. Second surgery is required to remove them after bone regeneration.	Healing Cap and Cover Cap is used by Connecting with the OB Anchor to fix OssBuilder during osseointegration. Second surgery is required to remove them after bone regeneration.		Healing Cap can be connected with Tenting Screw or OB Anchor to fix OssBuilder during osseointegration.
Material	Ti-6Al-4V (ASTM F136)	Pure Titanium Grade 4 (ASTM F67)	Ti-6Al-4V (ASTM F136)	Identical
Diameter (mm)	4.0, 5.0	4.0, 5.0	4.0	Identical
Height (mm)	7.0, 8.0	7.0, 8.0	4.3	Identical

Sterilization	Gamma Sterilization	Gamma Sterilization	Identical
Shelf Life	8 years	8 years	Identical
S.E.	**Similarities** The proposed Healing Cap has same dimension, function and indication for use; and is treated with same sterilization method and made by same manufacturer compared to the predicated Healing Cap (K172354). **Differences** The proposed Healing Cap is made of Ti-6Al-4V (ASTM F136) while the predicated Healing Cap is made to Ti Grade 4 (ASTM F67), but has made with same material compared to the predicated Cover Cap. ∴ The propose Healing Cap has different only in raw material compared to the predicated Healing Cap (K172354), but it has made with same material compared to the predicated Cover Cap (K172354). Except for this change/difference, its function, dimension, indication for use, etc. is same compared to the predicated; therefore, the proposed Healing Cap is substantially equivalent to the predicated Healing Cap (K172354).		

6. Indication for Use

   The OssBuilder System is used for space maintenance and stabilization of bone grafting material in an alveolar bone defect site.

7. Summary of Non-Clinical Performance Testing

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

   Biocompatibility evaluation
   Biocompatibility evaluation was conducted per 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." No additional biocompatibility testing for OssBuilder System was deemed necessary as the OssBuilder System is made of same material, chemical composition, manufacturing process and body contact with the predicated devices, Neo GBR System, K160991; and OssBuilder System, K172354.

   Sterilization Validation and Shelf-life
   All subject devices in OssBuilder System are delivered in sterile. Therefore, the shelf-life and sterilization validation was considered. We considered them by leveraging the data that of our prior submissions.

   Mechanical Properties
   Bench tests evaluated for OssBuilder System according to ASTM F543. Comparative mechanical testing was conducted to evaluate the mechanical properties including fracture load, insertion torque, axial pullout strength, torsional strength, breakage angle, removal torque, and self-tapping force following per ASTM F543 for worst-case insertion in block material that represents hard/soft bone. Mechanical properties

from bench tests of OssBuilder System found substantially equivalent to the predicate device.

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 OssBuilder System is substantially equivalent to the predicated devices as herein.