March 26, 2018

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

Re: K172354
Trade/Device Name: OssBuilder System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, NHA
Dated: February 20, 2018
Received: February 20, 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. 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.

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.

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,

Michael J. Ryan -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: K172354

Device Name: OssBuilder System

Indication for 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.

[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)

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) Summary

Date: March 24, 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	:	OssBuilder System
- Classification Name	:	Bone Plate
- Regulation Number	:	21CFR872.4760
- Devce Classification	:	Class II
- Classification Product Code	:	JEY
- Subsequent Product Code	:	NHA

3. Predicate Device

- Primary Predicate
  SMARTbuilder System, OSSTEM IMPLANT Co., Ltd. (K120951)

- Reference Devices
  SMARTBUILDER SYSTEM (SB1) (K130840)
  SB Anchor, OSSTEM Implant Co., Ltd. (K140600)

4. Description

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. It is consisted of OssBuilder, Healing Cap, Cover Cap, and OB Anchor.

The OssBuilder System is not indicated for permanent implantation.

Item	Content			
OssBuilder	Description	OssBuilder is 3D pre-formed titanium made non-resorbable membrane that helps bone augmentation by performing bone graft on the intraoral site with autogenous bone defect.		
	Material	Pure Titanium Grade 4 (ASTM F67)		
	Dimension (mm)	OB2	Proximal Buccal width Buccal length Buccal distance	4, 7, 10, 12 8, 9, 10, 12 7, 9 5.5
		OB3	Buccal width Buccal length Lingual length Buccal distance Lingual distance	10, 20 7, 9, 11 3.5, 4.5, 6, 7, 9, 11 5.5 3.7, 5.5
OB Anchor	Description	OB Anchor is used by connecting with implanted fixture to prevent intrusion of foreign material during the osseointegration. On the top of OB Anchor, it is connected with Healing Cap or Cover Cap to fix the OssBuilder.		
	Material	Ti-6Al-4V (ASTM F136)		
	Dimension (mm)	D (Ø)	3.1, 3.4, 3.5, 3.51, 3.53, 3.6, 3.63, 3.75, 3.87, 3.89, 4.0, 4.13, 4.25, 4.3, 4.37, 4.5, 5.0, 5.03, 5.13, 5.3	
		L	4.65, 4.85, 5, 5.35, 5.5, 5.65, 5.7, 6.0, 6.2, 6.5, 6.65, 6.7, 7.0, 7.2, 7.25, 7.5, 7.65, 7.7, 8.0, 8.15, 8.2, 8.5, 8.65, 9, 9.15, 9.5	
Healing Cap	Description	Healing Cap is used by connecting with the OB Anchor to fix OssBuilder during osseointegration and prevents intrusion of foreign material.		
	Material	Pure Titanium Grade 4 (ASTM F67)		
	Dimension (mm)	D (Ø)	3.98, 4, 5	
		H	3.38, 3.43, 4.03, 4.08, 7, 8	
Cover Cap	Description	Cover Cap is used by connecting with the OB Anchor to fix OssBuilder during osseointegration and prevents intrusion of foreign material.		
	Material	Ti-6Al-4V (ASTM F 136)		
	Dimension (mm)	D (Ø)	4.0	
		H	1.73, 4.3	

The OssBuilder System is compatible with OSSTEM Implant System, K161604; US SA Implant System, K161103; and NT/IT System, K081078.

5. Substantial Equivalence Matrixes

Change on the 'name' of the predicated devices			
	Proposed	**Predicated**	**Remark**
Device Name	Ossbuiler OB2	SMARTbuilder SB2 K120951	No other modifications happened except for the name of the device.
	Healing Cap	Healing Abutment K120951	
	OB Anchor	SB Anchor K140600	

	OssBuilder (OB3)	**SMARTbuilder (SB2)**	**Remark**
510(k) No.	Proposed	K120951	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Different
Indication for Use	OssBuilder System is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alvolar bony defect sites.	SMARTbuilder 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
Material	Pure Titanium Grade 2 (ASTM F67)	Pure Titanium Grade 2 (ASTM F67)	Identical
Width (D, mm)	10, 20	8, 9, 10, 12	Different
Sterilization	Gamma Sterilization	Gamma Sterilization	Identical
Shelf Life	8 years	5 years	Different
S.E.	**Similarities**		

	The proposed OssBuilder (OB3) is made of same material and has same indication for use and sterilization method; and is made by same manufacturer compared to the predicated SMARTbuilder (SB2) (K120951). **Differences** Application site is different between the proposed OssBuider (OB3) and the predicated, and it causes shape differences as a result. ∴ While there are shape differences between the proposed OssBuilder (OB3) and the predicated, the proposed device is made with same material and has same function and indication for use compared to that of the predicated; therefore, the proposed OssBuilder (OB3) is substantially equivalent to the predicated SMARTbuilder (SB2) (K120951) based on the results of the mechanical properties testing.

	Healing Cap	**Healing Abutment**	**Remark**
510(k) No.	**Proposed**	**Predicated (K120951)**	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Different
Indication for Use	OssBuilder System is a metal device intended for use with a detal implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	SMARTbuilder 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
Material	Pure Titanium Grade 4 (ASTM F67)	Pure Titanium Grade 4 (ASTM F67)	Identical
Diameter (mm)	4.0~5.0	4.0~7.0	Within the range of the predicated device.
Height (mm)	7.0~8.0	3.35~4.22	Different
Sterilization	Gamma Sterilization	Gamma Sterilization	Identical
Shelf Life	8 years	5 years	Different
S.E.	**Similarities** The proposed Healing Cap is made of same material and has same indication for use and sterilization method; and is made by same manufacturer compared to the predicated Healing Abutment (K120951).		

	Also, its diameter is within the range of that of the predicated device. **Differences** The proposed Healing Cap is used with internal type of anchor while the predicated Healing Abutment is used with external type of anchor. That is why the proposed device has longer height. ∴ While the proposed Healing Cap has different connection structure because it is compatible with different type of anchor than the predicated, its function and indication for use is same; therefore, the proposed Healing Cap is substantially equivalent to the predicated Healing Abutment (K120951) based on the results of the mechanical properties tests.

	Cover Cap	Cover Cap	Remark
510(k) No.	**Proposed**	**Predicated (K120951)**	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Identifier	SMCC415	SMCC415	Identical
Design			Identical
Indication for Use	OssBuilder System is a metal device intended for use with a detal implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	SMARTbuilder 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
Material	Ti-6Al-4V (ASTM F 136)	Pure Titanium Grade 4 (ASTM F67)	Different
Diameter (mm)	4.0	4.0	Identical
Height (mm)	1.73	1.52	Different
Sterilization	Gamma Sterilization	Gamma Sterilization	Identical
Shelf Life	8 years	5 years	Different
S.E.	**Similarities** The proposed Cover Cap has same identifier, design, indication for use, diameter, and sterilization method; and is made by same manufacturer compared to the predicated Cover Cap (K120951). **Differences** The material for the proposed Cover Cap is Ti-6Al-4V while the predicated is Ti Gr.4; and its height is different than that of the predicated. ∴ While the material and the height of the proposed Cover Cap is different from the predicated, its design function, and indication for use is same; therefore, the proposed Cover Cap is substantially equivalent to the		

	predicated Cover Cap (K120951) based on the results of the biocompatibility evaluations and mechanical properties testing.

	Cover Cap	Cover Cap	Remark
510(k) No.	**Proposed**	**Predicated (K120951)**	-
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Different
Indication for Use	OssBuilder System is a metal device intended for use with a detal implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	SMARTbuilder 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
Material	Ti-6Al-4V (ASTM F 136)	Pure Titanium Grade 4 (ASTM F67)	Different
Diameter (mm)	4.0	4.0	Identical
Height (mm)	4.3	1.52	Different
Sterilization	Gamma Sterilization	Gamma Sterilization	Identical
Shelf Life	8 years	5 years	Different
S.E.	**Similarities** The proposed additional shape of Cover Cap has same indication for use, diameter, and sterilization method; and is made by same manufacturer compared to the predicated Cover Cap (K120951). **Differences** The proposed Cover Cap is made of Ti-6Al-4V while the predicated is made of Ti Gr. 4. The proposed Cover Cap is used with internal type of anchor while the predicated Cover Cap is used with external type of anchor. That is why the proposed device has longer height. ∴ While the proposed Cover Cap is made with different material and has different connection structure because it is compatible with different type of anchor than the predicated, its function and indication for use is same; therefore, the proposed Cover Cap is substantially equivalent to the predicated Cover Cap (K120951) based on the results of the biocompatibility evaluations and mechanical properties testing.		

	OB Anchor	SB Anchor	Remark
510(k) No.	**Proposed**	**Predicated (K140600)**	-

Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Identical
Design			Different
Indication for Use	OssBuilder System is a metal device intended for use with a detal implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	SMARTbuilder 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
Material	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Identical
Diameter (mm)	3.1~5.0	3.3~5.1	Within the range of the predicated device.
Height (mm)	4.65~9.5	7.0~15	Different
Sterilization	Gamma Sterilization	Gamma Sterilization	Identical
Shelf Life	8 years	8 years	Identical
S.E.	**Similarities** The proposed OB Anchor is made of same material, has same indication for use and sterilization method; and is made by same manufacturer compared to the predicated SB Anchor (K140600). Also, its diameter is within the range of that of the predicated device. **Differences** The proposed device is internal type of anchor while the predicated device is external type of anchor. That is why the height of the proposed anchor is shorter than that of the predicated anchor. ∴ The design of the proposed OB Anchor is different because it is internal type of anchor while the predicated is external type of anchor, but it is made with same material and has same function and indication for use; therefore, the proposed OB Anchor is substantially equivalent to the predicated SB Anchor (K140600) based on the results of the mechanical properties tests.		

6. Indication for 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.

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 for OssBuilder System is not considered because the materials used for manufacturing OssBuilder System are titanium and titanium alloy which have been generally and widely used as a dental material such as implant for a long time. OssBuilder System is made of same material, chemical composition, and body contact with the predicated devices, SMARTbuilder System, K120951; SMARTbuilder System (SB1), K130840; and SB Anchor, K140600.

Sterilization Validation and Shelf-life

All subject devices in OssBuilder System are delivered in sterile. Therefore, the shelf-life and sterilization validation was considered. For the sterilization validation, it was performed accordance with worst-case chosen among subject devices and following ISO 11137. For the shelf-life of subject devices, we considered their validation of packaging materials by leveraging the data that of our prior submissions.

Mechanical Properties

Bench tests evaluated for OssBuilder System included Tensile Strength, Yield Strength, and Elongation. 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.