August 9, 2019

Osstem Implant Co., Ltd.
Jungmin Yoo
RA Manager
66-16, Bansong-ro 513beon-gil, Haeundae-gu
Busan, 612-070 Kr

Re: K182881
Trade/Device Name: Bone Screw, Bone Tack
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: July 18, 2019
Received: July 18, 2019

Dear Jungmin Yoo:

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,

Srinivas Nandkumar, Ph.D.
Acting 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

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510(k) Number: K182881

Device Name: Bone Screw, Bone Tack

Indication for Use:

Bone Screw is used to stabilize and fixate bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity. Bone Tack is indicated for use to stabilize and support bone graft and/or fractured bone segments with or without bone plates or titanium mesh in oral and maxillofacial site defects.

[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

K182881

Date: August 9, 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 : Bone Screw, Bone Tack
- Classification Name : Screw, Fixation, Intraosseous
- Regulation Number : 21CFR872.4880
- Devce Classification : Class II
- Classification Product Code : DZL

3. Predicate Device

- Primary Predicate
  Fixation Screw of Straumann GBR System, INSTITUT STRAUMANN AG (K011698)

- Reference Devices
  Bone Screw of Jeil Bone Fixation System, Jeil Medical Corporation (K050669)
  truTACK of ACE Tru-FIX Implant System, ACE Surgical Supply Co., Inc. (K080074)
  Osstem Implant System, OSSTEM Implant Co., LTd. (K161604)
  OssBuilder System, OSSTEM Implant Co., Ltd. (K172354)

4. Description

Bone Screw is using as anchor to fix the bone plate, membrane that cover bone material or block bone for bone regeneration or remodeling. *Bone Tack* is used to fix the membrane in GBR.

Item	Content		
Bone Screw	Description	Bone Screw is using as anchor to fix the bone plate, membrane that cover bone material or block bone for bone regeneration or remodeling. Ø1.4 diameter screw is for fixing membrane or bone plate, and Ø2.0 diameter screw is for fixing block bone.	
	Material	Ti-6Al-4V (ASTM F 136)	
	Dimension (mm)	D (Ø, implanted)	1.4, 1.95
		Length	4.0, 6.0, 8.0, 10, 12, 14, 16
Bone Tack	Description	Bone Tack is a stabilizer that can stably fix the membrane in GBR.	
	Material	Ti-6Al-4V (ASTM F 136)	
	Dimension (mm)	D (Ø, Head)	2.5
		Length	3.0

5. Substantial Equivalence Matrixes

	Bone Screw	Straumann GBR System	Jeil Bone Fixation System	Remark
510(k)	Proposed	Primary Predicate (K011698)	Reference Device (K050669)	-
Manufacturer	Osstem Implant Co., Ltd.	Straumann USA	Jeil Medical Corporation	-
Design				Similarity
Indications for Use Statement	Bone Screw is used to stabilize and fixate bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity.	The Straumann Guided Bone Regeneration (GBR) System is used to stabilize and fixate bone grafts, bone filling materials, and/or barrier	The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue	Similarity. Small changes are due to differences in component-specific language.

		membranes used for regeneration of bone in the oral cavity. The GBR technique can make it possible for the placement of dental implants in previously unsuitable sites.	regeneration in the oral cavity. Single patient use only.	
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium (Ti Grade 4, ASTM F67)	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Identical as that of the reference device
Screw Diameter	1.4 mm 1.95 mm	1.2 mm 1.5 mm	1.4 mm 1.6 mm 2.0 mm	Different but the range of screw diameter and the screw length is within the permissible range of the predicates devices; therefore, the dimensions for the proposed devices are substantially equivalent to the predicates devices
Screw Length	Ø1.4: 4.0 mm 6.0 mm 8.0 mm Ø1.95: 8.0 mm 10.0 mm 12.0 mm 14.0 mm 16.0 mm	3.0 mm 4.0 mm 5.0 mm 7.0 mm 8.0 mm 9.0 mm 10.0 mm 12.0 mm 14.0 mm	4.0 mm 5.0 mm 6.0 mm 8.0 mm 10.0 mm 12.0 mm 14.0 mm 16.0 mm	
Single Use	Yes	Yes	Yes	Similarity
Sterility	Sterile (Shelf life: 8 years)	Non-sterile (Sterilize before use)	Non-sterile (Sterilize before use)	Different
Principle of Operation	The function of proposed devices is used in application for maintaining the relative position of and/or bone grafts in reconstruction of maxillary and/or mandibular areas	The function of predicate devices is used in application for maintaining the relative position of and/or bone grafts in reconstruction of maxillary and/or mandibular areas	The function of predicate devices is used in application for maintaining the relative position of and/or bone grafts in reconstruction of maxillary and/or mandibular areas	Similarity
S.E.	**Similarities** The proposed devices have similar indications for use with that of the primary predicate, Straumann GBR System of Straumann USA (K011698). The proposed devices have similar principle of operation which is to function for maintaining the relative position of and/or bone grafts in reconstruction of maxillary and/or mandibular areas. The proposed devices are made with same material and have similar designs compared to that of the predicates. The proposed devices are single use only which is the same way as the			

	predicates. **Differences** The proposed devices have different dimensions compared to that of the predicates, but the range of screw diameter and screw length is within the permissible range of the predicates devices, Straumann GBR System of Straumann USA (K011698) and Jeil Bone Fixation System of Jeil Medical Corporation (K050669). The proposed devices are gamma sterilized while the predicates are delivered in non-sterile which required sterilization prior to use. ∴ While given dimensions are different with that of the predicates (K011698 and K050669), the proposed devices have similar indications for use, similar shape and principle of operation; and are made with same materials compared to that of the described predicates. Therefore, the proposed devices are substantially equivalent to the predicates above.

	Bone Tack	**ACE Tru-FIX Implant System**	**Remark**
510(K)	Proposed	Reference Device (K080074)	-
Manufacturer	Osstem Implant Co., Ltd.	ACE Surgical Supply Co., Inc.	Different
Design			Similarity
Indications for Use Statement	It is indicated for use to stabilize and support bone graft and/or fractured bone segments with or without bone plates or titanium mesh in oral and maxillofacial site defects.	It is indicated for use to stabilize and support bone graft and or fractured bone segments with or without bone plates or titanium mesh in oral and maxillofacial site defects.	Similarity
Material	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Titanium Alloy (Ti-6Al-4V, ASTM F136)	Similarity
Head Diameter	2.5 mm	2.5 mm	Similarity
Length	3.0 mm	3.0 mm 5.0 mm	Similarity
Single Use	Yes	Yes	Similarity
Sterility	Sterile (Shelf life: 8 years)	Sterile (Shelf life: unknown)	Similarity
Principle of Operation	The function of proposed device is used in application for fixating or stabilizing barrier membranes in GBR	The function of proposed device is used in application for fixating or stabilizing barrier membranes in GBR	Similarity
S.E.	**Similarities**		

	The proposed device has same indication and function, and is made of same material compared to that of the predicate device, ACE Tru-FIX Implant System of ACE Surgical Supply Co., Inc. (K080074). Proposed device has same head diameter and length, and supplied in sterile compared to that of the predicate device. **Differences** The proposed device has one length option while the predicates have two options in length with having same diameter. ∴ The proposed device has same dimension, made of same material, and has similar indications and priniciple of operation compared to that of the predicate device; therefore, the proposed device is substantially equivalent to the predicate above.

6. Indications for Use

Bone Screw is used to stabilize and fixate bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity. Bone Tack is indicated for use to stabilize and support bone graft and/or fractured bone segments with or without bone plates or titanium mesh in oral and maxillofacial site defects.

7. Summary of Non-Clinical Performance Testing

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

Biocompatibility evaluation
Biocompatibility testing was considered following 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 suite of standards and leveraged from reference device K172354.

Sterilization Validation and Shelf-life
All subject devices are delivered sterile. Sterilization validation and shelf-life was considered following the ISO 11137 and ISO 11607 suites of standards.
Endotoxin batch testing is in place per the FDA Guidance Document *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*.

Mechanical Properties
Mechanical testing was evaluated following ASTM F543 with the worst case scenario.

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 Bone Screw and Bone Tack are substantially equivalent to the predicated devices as herein.