December 1, 2017

Biotem Co., Ltd.
% Joyce Bang
Consultant
Provision Consulting Group, Inc.
14071 Peyton Dr. #967
Chino Hills, California 91709

Re: K171185
Trade/Device Name: IR Type Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 28, 2017
Received: October 31, 2017

Dear Joyce Bang:

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,

Andrew I. Steen -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171185

Device Name
IR Type Implant System

Indications for Use *(Describe)*

IR Type Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. IR Type Implant System is for one stage surgical procedures. It is intended for delayed loading. IR Implant System is intended only for straight placement with no correction of angulation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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15. 510(K) SUMMARY

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Prepared Date: 11-30-2017

Device Information:
Device Name: IR Type Implant System
Classification Name: Endosseous Dental Implant
Common Name: Endosseous Dental Implant
Classification: Class II
Product Code: DZE
Subsequent Product Code: NHA
Regulation number: 21 CFR 872.3640

Predicate Device:
SS System (K062051) manufactured by Osstem Implant Co., Ltd.

Indications for use
IR Type Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. IR Type Implant System is for one stage surgical procedures. It is intended for delayed loading. IR Implant System is intended only for straight placement with no correction of angulation.

Device Description

IR Type Implant System is a dental implant system made of of CP Ti Gr. 4 intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. The implant may be used to replace one or more missing teeth. The system is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface of the system has been treated with R.B.M (Resorbable Blast Media).

Endosseous Diameter	Endosseous Length(mm)
Ø3.5	8.5 , 10.0 , 11.5 , 13.0 , 15.0
Ø 4.1	7.5 , 8.5 , 10.0 , 11.5 , 13.0 , 15.0
Ø 4.8	7.5 , 8.5 , 10.0 , 11.5 , 13.0 , 15.0
Ø 5.5	7.5 , 8.5 , 10.0 , 11.5 , 13.0 , 15.0

Substantial Equivalence Comparison Chart

		Subject Device	Predicate Device
510(k) Number		Not available yet	K062051
Device Name		IR Type Implant System	SS System
Manufacturer		Biotem Co., Ltd.	Osstem Implant Co., Ltd.
Indications for Use		IR Type Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. IR Type Implant System is for one stage surgical procedures. It is intended for delayed loading. IR Implant System is intended only for straight placement with no correction of angulation.	SS System is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. SS System is for one stage surgical procedures. It is not for immediate load.
Design		Internal Octa Tapered	Internal Octa Tapered
Material		CP Ti Gr 4 ASTM F67	CP Ti Gr 4 ASTM F67
Sterilization		Gamma sterilization	Gamma sterilization
Fixture Diameter (mm)		Ø 3.5, 4.1, 4.8, 5.5	Ø 3.5-6.0
Fixture Length (mm)		7.5, 8.5, 10.0, 11.5, 13.0, 15.0	6.0-15.0
Abutment	**Diameters**	Ø 4.8. 6.0, 6.5 mm	Ø 4.8, 6.0, 6.5 mm
	Lengths	2.0, 3.0, 4.0, 5.5 , 6.0 , 7.0mm	2.0, 4.0, 5.5, 7.0mm
	Angled	0°	20°
Attachment		Various abutments and components	Various abutments and components
Surface treatment		RBM	RBM
Product Code		DZE, NHA	DZE, NHA

Basis for Substantial Equivalence

IR Type Implant System has a substantially equivalent intended use as the identified predicate (K062051). Both are used for mandible and maxilla endosseous dental implant and accessories. The IR Type Implant System is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments.

The subject and predicate devices are similar in size, surface treatment and materials.

When compared with predicate devices, no new questions of substantially equivalence have been raised for the IR Type Implant System.

Non- Clinical Testing

The subject device was tested to evaluate its performance as below.

• Sterilization Validation testing for sterile devices (fixtures) has been performed in accordance with ISO11137, ISO 11737-1& ISO 11737-2 for gamma sterilization

• Steam Sterilization validation for non-sterile devices (abutments) has been performed in accordance with ISO 17665-1 and IS 17665-2.

• Surface Characteristics Test Report - Chemical and SEM image analyses have been performed to verify that there is no residual after RBM treatment on the fixtures.

• Cytotoxicity Test performed according to ISO 10993-5:2009

• Sensitization test performed according to ISO 10993-10:2010

• LAL Endotoxin lot release testing according to USP <85>

• Shelf Life Testing performed according to ISO 11607

Those tests have been performed to evaluate the substantial equivalence in the surface characteristics compared to the predicate device. The result of the above tests have met the criteria of the standard, and proved the substantial equivalence with the predicate device. Non- clinical testing consisted of performance of testing in accordance with the FDA guidance "Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments." The results of the non-clinical testing demonstrate that the subject device is substantially equivalent to the predicate device

Conclusion

The subject devices and the predicate devices have the similar intended use and have the similar technological characteristics. The subject and predicate implants are all made of commercially pure titanium and have the similar surface treatments. Overall, the IR Implant System has the following similarities to the predicate devices:

- has the similar me intended use,
- uses the similar operating principle,
- incorporates the similar basic design,
- incorporates the similar material and the surface treatment.

Based on the similarities, we conclude that the IR Implant System is substantially equivalent to the predicate device.