Biotem Co.,Ltd.
% Joyce Bang
Consultant
Provision Consulting Group Inc.
1370 Valley Vista Dr.
Suite 200
Diamond Bar, California 91765

February 9, 2018

Re: K171179
Trade/Device Name: BR Type Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 2, 2017
Received: January 10, 2018

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,

Mary S. Runner -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)*
K171179

Device Name
BR Type Implant System

Indications for Use *(Describe)*

The BR 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. BR Type Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

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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510(K) SUMMARY

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Date Prepared: 02/08/2018

Device Information:

Device Name: BR 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: K062030, US System manufactured by Osstem Implant Co., Ltd.

Reference Device: K172240, SPI Dental Implant System manufactured by MSI France

Indication for use

The BR 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. BR Type Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

Device Description

Fixture
The BR Implant System is a dental implant system made of CP Ti Gr 4 / ASTM F67, intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. The surface of the implants has been treated with R.B.M (Resorbable Blast Media) with acid etch. The BR Type Implant System is offered in the following sizes..

Platform	Body Diameter	Total Length (mm)
Ø 3.5	Ø 3.3	8.5, 10.0, 11.5, 13.0, 15.0
Ø 4.1	Ø 3.7	7.5, 8.5, 10.0, 11.5, 13.0, 15.0
Ø 4.1	Ø 4.0	7.5, 8.5, 10.0, 11.5, 13.0, 15.0
Ø 5.0	Ø 5.0	7.5, 8.5, 10.0, 11.5, 13.0, 15.0
Ø 5.1	Ø 5.0	7.5, 8.5, 10.0, 11.5, 13.0, 15.0
Ø 5.1	Ø 6.0	7.5, 8.5, 10.0, 11.5, 13.0, 15.0

Abutment

Each product line includes corresponding abutments in multiple designs (Cover Screws, Healing Abutments, Angled Abutments, Cemented Abutments (Hex, Non-hex), and Solid Abutments) for restorations. Small diameter implants and angled abutments are not recommended for the posterior region. They are made of Titanium Grade 4 / ASTM F67, and provided as non-sterile.

Abutments	Connection	Sizes		
		Angulation (°)	Cuff Heights (mm)	Platform diameter (Ø)
Angled abutment	Assembled with Fixture and angled Abutment by connecting abutment body with set screw. The connection type is External Hexagon shape.	15, 25	2, 4	4.0, 5.0, 6.0
Cemented Abutment	Assembled with fixture and cemented abutment by connecting abutment body with set screw. The connection type is External Hexagon shape.	0	1,2,3,4	4.0, 5.0, 6.0
Healing Abutment	Assembled with Fixture and Healing Abutment by inserting the screw part. And the connection is External Hexagon shape.	0	2,3,4,5,7	4.0, 5.0, 6.0
Cover Screw	Assembled with Fixture by inserting screw part. And the connection is External Hexagon shape	0	2.7	3.5, 4.1, 5.0, 5.1

Substantial Equivalence Comparison Chart

	Subject Device	Predicate Device
510(k) Number	K171179	K062030
Device Name	BR Type Implant System	US System
Manufacturer	Biotem Co., Ltd.	Osstem Implant Co., Ltd.
Indications for Use	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. BR Type Implant System is for single and two stage surgical procedures. It is intended for delayed loading.	US system and SSII mini are 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. US System is for two stage surgical procedures. It is not for one stage surgery or immediate load. The SSII mini is for one and two stage surgical procedures. It is not for immediate load.
Design	External Hex Type	External Hex Type
Material	CP Ti Grade 4 ASTM F67	CP Ti Gr 4 ASTM F67
Sterilization	Gamma sterilization	Gamma sterilization
<u>Fixture</u> Platform(Ø) x Body diameter(Ø) x hex(mm) x length(mm)	Ø3.5, x Ø3.3 x 2.4mm x (8.5mm, 10mm, 11.5mm, 13mm, 15mm)	Ø3.5, x Ø3.3 x 2.4mm x (8.5mm, 10mm, 11.5mm, 13mm, 15mm)
	Ø4.1, x (Ø3.75, Ø4.0) x 2.7mm x (7.5mm, 8.5mm, 10mm, 11.5mm, 13mm, 15mm)	Ø4.1, x Ø4.0 x 2.7mm x (7mm, 8.5mm, 10mm, 11.5mm, 13mm)
	Ø5.1, x (Ø5.0, Ø6.0) x 3.4mm x (7.5mm, 8.5mm, 10mm, 11.5mm, 13mm, 15mm)	Ø5.1, x Ø5.0 x 3.4mm x (6mm, 7mm, 8.5mm, 10mm, 11.5mm, 13mm)
	Ø5.0, x Ø5.0 x 2.7mm x (7.5mm, 8.5mm, 10mm, 11.5mm, 13mm, 15mm)	Ø5.0, x Ø5.0 x 2.7mm x (6mm, 7mm, 8.5mm, 10mm, 11.5mm, 13mm)
<u>Angled abutment</u> Platform(Ø) x cuff size(mm) x Length(mm) x Angulation(°)	Ø4.0 x (2mm, 4mm) x (7mm) x (15°, 25°)	Ø4.0 x (2mm, 4mm) x (7mm) x (15°, 25°)
	Ø5.0 x (2mm, 4mm) x (7mm) x (15°, 25°)	Ø5.0 x (2mm, 4mm) x (7mm) x (15°, 25°)
	Ø6.0 x (2mm, 4mm) x (7mm) x (15°, 25°)	Ø6.0 x (2mm, 4mm) x (7mm) x (15°, 25°)
<u>Cemented Abutment</u> Platform(Ø) x cuff size(mm) x length(mm)	Ø 4.0 x (2mm, 4mm) x (6mm ,7.5mm)	Ø4.0 x (2mm, 4mm) x (7.5mm)
	Ø5.0 x (1mm, 2mm, 3mm, 4mm) x (4mm, 5.5mm, 7mm)	Ø5.0 x (1mm, 2mm, 3mm, 4mm) x (4mm, 5.5mm, 7mm)
	Ø6.0 x (1mm, 2mm, 3mm, 4mm) x (4mm, 5.5mm)	Ø6.0 x (1mm, 2mm, 3mm, 4mm) x (4mm, 5.5mm)
<u>Healing Abutment</u> Platform(Ø) x cuff size(mm)	Ø4.0 x (2mm, 4mm)	Ø4.0 x (3mm, 5.5mm)
	Ø5.0 x (2mm, 3mm, 4mm, 5mm, 7mm)	Ø5.0 x (2mm, 3mm, 4mm, 5.5mm, 7mm)
	Ø6.0 x (2mm, 3mm, 4mm, 5mm)	Ø6.0 x (3mm, 5.5mm)
Surface treatment	RBM	RBM
Product Code	DZE, NHA	DZE, NHA

The difference in the Indications for Use Statement regarding “immediate loading” and “delayed loading” have been made to reflect the more recent clearances to include positive indications in the Indications for Use Statement.

The BR Type Implant System has a substantially equivalent intended use as the identified predicate (K062030). Both are used for mandible and maxilla endosseous dental implant and accessories. The BR 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 both bone-level implants that share similar neck design and cutting edge. The subject and predicate devices are similar in size, surface treatment and materials. The Ø5.0 and Ø6.0 fixtures (implants) with the length of 15mm technological features (diameter and length) are similar to the reference device K172240.

Non-Clinical Test data

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

- Sterilization Validation testing for sterile devices (fixtures) has been performed in accordance with ISO 11137, 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 ISO 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.
- Shelf-life and packaging material has been validated according to ISO 11607, ISO 11137 and ISO 11737. Accelerated aging, strength, and integrity were performed to ASTN F1980, ASTM D882, ASTM F88, ASTM F1140, ASTM F1929, ASTM F2096 and ASTM F1608. Shelf life for the fixture was determined to be 3 years.
- Comparative Fatigue testing of the subject device and predicate device has been performed in accordance with ISO 14801:2007.
- Cytotoxicity Test performed according to ISO 10993-5:2009
- Sensitization test performed according to ISO 10993-10:2010

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.

Conclusions

Overall, the BR Type Implant System has the following similarities to the predicate devices:
*has the same intended use,
*uses the same operating principle,
*incorporates the same basic design,

*incorporates similar material and the surface treatment.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, we conclude that the BR Type Implant System is substantially equivalent to the predicate device.