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

January 31, 2018

Re: K171297
Trade/Device Name: AR_N 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 4, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171297

Device Name
AR_N Type Implant System

Indications for Use *(Describe)*
AR_N 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. AR_N Type Implant System is for two stage surgical procedures. It is intended for delayed load.

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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16. 510(K) SUMMARY

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Date Prepared: January 26, 2018

Device Information:
Device Name: AR_N 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 devices
• CMI IS Implant System (K113554) manufactured by Neobiotech Implant Co., Ltd.

Indication for use
AR_N 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. AR_N Type Implant System is for two stage surgical procedures. It is intended for delayed loading.

Device Description
The AR_N Type Implant System is a dental implant system made of CP Ti Gr 4 per 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 implants may be used to replace one or more missing teeth. The surface of the implants has been treated with RBM (Resorbable Blast Media). The AR_N Type Implant System is offered in the following sizes.

Platform	Body Diameter	Total Length (mm)
Ø 3.7	Ø 3.5	7.5, 8.5, 10.0, 11.5, 13.0, 15.0
Ø 4.2	Ø 4.0	7.5, 8.5, 10.0, 11.5, 13.0, 15.0
Ø 4.6	Ø 4.5	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

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 (Hex) by inserting Abutment body with set screw. The connection type is internal Hexagon shape.	15, 25	2, 4	4.5 ~5.8
Cemented Abutment (Hex)	Assembled with fixture and cemented abutment (Hex) by inserting abutment body with set screw. The connection type is Internal Hexagon shape	0	1~6	4.5~6.5
Cemented Abutment (Non-Hex)	Assembled with Fixture and Cemented Abutment (Non-Hex) by inserting Abutment body with set screw. The connection type is internal Non-Hexagon shape.	0	1~6	4.5~6.5
Healing Abutment	Assembled with Fixture and Healing Abutment by inserting the screw part. And the connection is internal Hexagon shape	0	1~5	4.5~6.5
Solid Abutment	Assembled with fixture by inserting set screws. The connection type is internal Hexagon shape.	0	1~6	4.5~6.5
Cover Screw	Assembled with Fixture by inserting screw part. And the connection is internal Hexagon shape.	0	2.7	2.8 -3.3
Set screw	Connection with abutment with screw	0	10 (length)	2.1, 2.5

Substantial Equivalence Comparison Chart

	Subject Device	**Predicate Device**
510(k) Number	K171297	K113554
Device Name	AR_N Type Implant System	CMI IS Implant System
Manufacturer	Biotem Co., Ltd.	Neobiotech Co., Ltd.

Principles of Operation		Subject device is an endosseous implants and are integrated in the bone (osseointegration). They are intended to be used for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment for anchoring or supporting tooth replacements to restore chewing function.	Predicate device is an endosseous implants and are integrated in the bone (osseointegration). They are intended to be used for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment for anchoring or supporting tooth replacements to restore chewing function.
Indications for Use		AR_N 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. AR_N Type Implant System is for two stage surgical procedures. It is intended for delayed load.	The CMI Implant IS 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. IS System is dedicated for two stage surgical procedures and for immediate loading when there is good primary stability and an appropriate occlusal load. Also, implants with diameters larger than 5 min are indicated for molar regions.
Design		Internal Hex Submerged Macro thread	Internal Hex Submerged Macro thread
Material		CP Ti Gr 4 ASTM F67	CP Ti Gr 4 ASTM F67
Fixture Sterilization		Gamma sterilization	Gamma sterilization
Fixture Diameter (mm)		Ø3.7 - 5.1	Ø3.5 - 8.0
Fixture Length (mm)		7.5 - 15.0	7.0 - 15.0
Surface treatment		RBM	RBM
	Diameters	Ø4.5 - 6.5mm	Ø3.5 - 6.5
	Lengths	4.0 - 9.0mm	4.0-9.0mm
Abutment	**Angled**	15°, 25°	15°,25°
Abutment material		CP Ti Gr 4 ASTM F67	CP Ti Gr 4 ASTM F67
Abutment sterilization		Non-sterile	Non-sterile
Product Code		DZE, NHA	DZE, NHA

	Subject abutments **Biotem Product (AR N type)**			Predicate abutments **NEO BIOTECH Product (IS-II type)**		
	Platform diameter (Ø)	Cuff heights (mm)	Angulation (°)	Platform diameter (Ø)	Cuff heights (mm)	Angulation (°)
Healing abutment	4.5~6.5	1~5	0	4.0~6.0	2~7	0
Cemented abutment (hex)	4.5~6.5	1~6	0	4.5~6.5	1~4	0
Cemented abutment (non-hex)	4.5~6.5	1~6	0	4.5~6.5	1~4	0
Solid abutment	4.5~6.5	1~6	00	4.5~6.5	1~7	0
Angled abutment	4.5 ~5.8	2, 4	15, 25	4.5~5.7	2,3,4	15, 25

Basis for Substantial Equivalence

The AR_N Type Implant System has a substantially equivalent intended use as the identified predicate. Both are used for mandible and maxilla endosseous dental implant and accessories. The AR_N 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. They all share same internal hexagon submerged connection system. The subject and predicate devices are both bone-level implants that share same tapered body design and cutting edge. The subject and predicate devices are similar in size, same surface treatment and materials.

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, SIO 11737-1& ISO 11737-2 for gamma sterilization
- Steam Sterilization validation for non-sterile devices (abutments) has been performed in accordance with ANSI/AAMI ST79.
- 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.
- 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 AR_N 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 the same 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 AR_N Type Implant System is substantially equivalent to the predicate device.