February 21, 2020

Biotem Co., Ltd.
% Joyce Bang-Kwun
Consultant
Provision Consulting Group Inc.
3350 Shelby St. Suite 200
Ontario, California 91764

Re: K190641
Trade/Device Name: AR_N SLA Type Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: January 21, 2020
Received: January 27, 2020

Dear Joyce Bang-Kwun:

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,

for Srinivas Nandkumar, Ph.D.
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

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)*
K190641

Device Name
AR_N SLA Type Implant System

Indications for Use *(Describe)*
AR_N SLA 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 SLA 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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510(K) Summary (K190641)

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Revision date: Feb 18, 2020

Device Information:
- Device Name: AR_N SLA Type Implant System
- Classification Name: Endosseous Dental Implant
- Common Name: Endosseous Dental Implant
- Classification: Class II
- Product Code: DZE
- Regulation number: 21 CFR 872.3640

Primary Predicate
- AR_N Type Implant System (K171297)

Reference devices
- INNO SLA Submerged Implant System (K132242)
- External Hex Implants (K163634)

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

Device Description
The AR_N SLA 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 SLA(Sandblasted with Large-grit and Acid-etching). The AR_N SLA Type Implant System is offered in the following sizes. Subject implant bodies are to be used only with all abutments cleared in the primary predicate submission, and the cover screw and abutment screw to be used are the same as cleared in the primary predicate.

Substantial Equivalence Comparison Chart (fixtures)

	AR_N SLA Implant system	Primary Predicate	Reference device	Reference device
510(k) Number	K190641	K171297	K132242	K163634
Device Name	AR_N SLA Type Implant System	AR_N Type Implant System	INNO SLA Submerged Implant System	Ex Hex Cylindrical Internal Drive from K163634
Manufacturer	Biotem Co., Ltd.	Biotem Co., Ltd.	Cowellmedi Co., Ltd.	Southern Implants (Pty) Ltd.
Indications for Use	AR_N SLA 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 SLA Type Implant System is for two stage surgical procedures. It is intended for delayed load.	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.	The INNO SLA Submerged 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, this system is intended for delayed loading. The implants with diameters larger than 5.0mm are intended to be surgically placed in the maxillary or mandibular molar areas for the purposed of providing prosthetic support for dental restorations (Crown, bridge, and overdentures) in partially or fully edentulous individuals. These implants are intended to be used where smaller implants have failed.	Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.
Connection type	Internal Hex	Internal Hex	Internal Hex	External hex

Design	Internal Hex Submerged Macro thread	Internal Hex Submerged Macro thread	Internal Hex Submerged Macro thread	Straight, Threaded
Material	CP Ti Gr 4 ASTM F67	CP Ti Gr 4 ASTM F67	CP Ti Gr 4 ASTM F67	CP Ti
Fixture Body Diameter (mm)	3.7, 4.2, 4.6, 5.1, 6.0	3.7, 4.2, 4.6, 5.1	3.7, 4.2, 4.6, 5.1, 6.0	3.75, 5.0, 6.0
Fixture Length (mm)	7.5, 8.5, 10, 11.5, 13, 15	7.5, 8.5, 10, 11.5, 13, 15	7, 7.5, 8, 9.5, 10, 11.5, 12, 14	Ø3.75: 7, 8.5, 10, 11.5, 13, 15, 18, 20 Ø5.0: 6, 7, 8.5, 10, 11.5, 13, 15, 18 Ø6.0: 7, 8.5, 10, 11.5, 13, 15
Surface treatment	SLA	RBM	SLA	Grit blasted Machine collar versions available

Comparison Analysis

Similarities:
The subject device (K190641) and the primary predicate (K171297) both have the same principle of operation, fundamental technology, intended use, indications for use, packaging material/process, product code, connection type, method of sterilization, material (titanium), and the dimensions except 6.0 mm of diameter.

Differences:
One difference between the subject device and the primary predicate device is the surface treatment. The surface treatment method of the predicate fixture is RBM (Resorbable Blasting Media) whereas the surface treatment method of the subject device is SLA (Sandblasted with Large-grit and Acid-etching). To support this discrepancy, K132242 was added as a reference device which was treated with SLA method. Another difference is that the fixtures with 6.0mm in diameter have been added to the subject device. To support this dimensional discrepancy, the reference device (K163634) is compared. K163634 has fixtures with 6.0mm and lengths in a range of 7-15mm. Therefore, the surface and dimensional differences do not impact substantial equivalence.

The reference devices' Indications for Use are slightly differ from the subject Indications for Use. However, they do not include any component-specific language relevant to the difference in technology they are being used to support; therefore, the differences do not impact substantial equivalence.

Non-Clinical Test data
The subject device was tested to evaluate its performance and demonstrate substantial equivalence 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
- Surface Characteristics Test Report - Chemical and SEM image analyses have been performed to verify that there is no residual after SLA treatment on the fixtures.
- Fatigue testing of the predicate device has been performed in accordance with ISO 14801:2007. Since the raw materials, manufacturing process except surface modification, sterilization method, packaging materials and worst-case geometries are identical between the subject and predicate devices, the test reports can be leveraged for the subject device. The difference in surface treatment is not expected to impact fatigue performance.
- Biocompatibility testing per ISO 10993-1, ISO 10993-5:2009, ISO 10993-10:2010
- Pyrogenicity testing - All recommended information for an implanted device related to pyrogenicity is provided in accordance with a reference to the FDA Guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile."
- LAL bacterial endotoxin testing per USP 41 <85>, rev. 05/2018, USP 41 <161>, rev. 05/2018, ANSI/AAMI ST72:2011
- Shelf Life testing has been conducted on the predicate devices (K171297) in accordance with ISO 11607, ISO11137, ASTM F1980. Since the raw materials, manufacturing process, sterilization method, packaging materials and methods are identical between the subject and predicate devices, and surface treatment is not expected to impact shelf life, the test reports can be leveraged for the subject device. To support the accelerated aging shelf life, real aging test has been initiated.

The results of the non-clinical testing demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion:

The AR_N SLA type implant system constitutes a substantially equivalent medical device. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, AR_N SLA type implant system and its predicates are substantially equivalent.