DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 22, 2017

GP Implants
Pivovarov German
Beeri 12A
Ap7 Netanya
ISRAEL

Re: K162299
Trade/Device Name: Spiral Shape Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 19, 2017
Received: May 24, 2017

Dear Pivovarov German:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Andrew I. Steen -S

for Lori A. Wiggins, MPT, CLT
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K162299

Device Name
Spiral Shape Dental Implant System

Indications for Use *(Describe)*
The Spiral Shape Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510k Summary K162299
June 22, 2017
Spiral Shape Dental Implant System

Name and address: GP Implants
Beeri 12A,
Ap7 Netanya, Israel
Contact Person: Pivovarov German
Phone Number: +972542079520
Name of device: Spiral Shape Dental Implant System
Classification Name: Endosseous dental implants
CFR: 21 CFR 872.3640
Product Code: DZE, NHA

Device Description: Spiral Shape Dental Implant System is an internal hex implant system which comes in 3.3, 3.7, 4.2, 5.0, and 6.0 diameter. The implants come in lengths of 8, 10, 11.5, 13 and 16 (no 6.0 diameter in 16). Both straight and angled abutments are available.

The implant is a conical shape one with a grit blasted and acid etched surface. Standard abutments, standard narrow abutments, standard shoulder abutments, standard wide shoulder abutments, multi-unit abutments, ball attachments, healing caps and standard 15° and 25° abutments are included in the system.

Indications for Use: The Spiral Shape Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Testing Summary: Dynamic fatigue testing according to ISO 14801 was conducted to determine the abutments are strong enough for their intended use. Predicate device comparative testing was also provided. Surface analysis according to the FDA guidance document was done including SEM and EDS. Sterilization validation according to ISO 11137-1 and 11137-2 was conducted on the implants. Abutment steam sterilization validation was done according to ISO 17665-1 and ISO 17665-2. Package integrity testing according to ASTM F1929-12 and accelerated aging according to ASTM F1980-07 was conducted. Materials used in the product meet ASTM F136 and the biocompatibility was demonstrated by testing the cytotoxicity according to ISO 10993-5. Endotoxin testing according to USP 161 was conducted.

Predicate Device: Alpha-Bio Tec Dental Implant System K063364
Reference Predicate: Ditron Dental Implants K161497

Substantial Equivalence:

Spiral Shape Dental Implant System is substantially equivalent to Apha-Bio Tec in indications for use, materials, design, and fatigue performance.

Company	Spiral Shape Dental Implant System	Alpha-Bio Tec Dental Implant System K063364 (SPI)	Ditron Dental Implants K161497
Indications for Use	The Spiral Shape Dental implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Alpha-Bio Tec Dental implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. SPI implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Ditron's dental implants and abutments are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.
Implant Diameters	3.3, 3.7, 4.2, 5, 6	3.3, 3.75, 4.2, 5, 6	3.3
Material of devices included in the submission	Ti-6AL-4V ELI	Ti-6AL-4V ELI	Ti-6AL-4V ELI
Type of abutment and maximum angulation	Pre-manufactured of no more than 25°	Pre-manufactured of no more than 25°	Pre-manufactured of no more than 25°
Interface type/shape	Internal hex	Internal hex	Internal hex

	GP Implants Device	**Alpha Bio Tec Device**
Spiral Shape Internal Hex Implants	Spiral Shape Implants Diameters of 3.3, 3.7, 4.2, 5, and 6mm	SPI Implants Diameters of 3.3, 3.75, 4.2, 5, and 6 mm
Cover screw	Cover screw	Alpha Bio cover screw
Multi-Unit Abutments	Multi-unit abutments in heights of 1,2,3 and 4 mm	AlphaLoc Attachment in heights 0.5, 1,2,3,4,5,6,and 7mm
Ball attachments	Ball attachments in heights of 1,2,3,4,5, and 6mm	Ball attachments in heights of 0.5,2,3,4,5, and 6mm
Healing Caps 4.5	Healing cap in 2 and	Standard Healing

diameter	7mm height	Abutment in heights of 2,3,4,5,6, and 7mm
Healing Caps 5.5 diameter	Healing cap in 2,3,4,5,6,and 7	Wide healing abutment in heights of 3 and 5mm
Standard Titanium Abutment	Standard Titanium Abutment with height of 7mm	TLA with height of 8.5mm
Standard Narrow Abutment	Standard narrow abutment with heights of 7,9, and 11mm	TLASP1 Height 8.9 TLASP2 Height 9.9 TLASP3 Height 10.9 TLASP4 Height 11.9
Standard Shoulder Abutment	Standard shoulder abutment in heights of 1,2,3 and 4mm	ETLASP1 height 1 ETLASP2 height 2 ETLASP3 height 3 ETLASP4 height 4
Standard Wide Shoulder Abutment	Standard Wide Shoulder Abutment with heights of 1,2,3,and 4mm	TLA02 height of 2mm TLA04 height of 4mm
Standard 15° Abutment	Standard 15° Abutment with heights of 8, 12, and 13mm	TLA15 height of 8.5mm TLAL15 height of 11.5mm
Standard 25° Abutment	Standard 25° Abutment with heights of 9 and 12mm	TLA25 height of 8.5mm TLAL25 height of 11.5mm

Conclusion:

Spiral Shape Dental Implant System is substantially equivalent to Alpha-Bio Tec SPI Dental Implant System. They both have the same indications for use, are of the same material, have internal hex and connections. The abutments, healing caps, and angled abutments are offered in similar designs and heights. Performance testing demonstrates substantial equivalence to the identified predicate devices.