December 6, 2019

JJ Implants
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K190552
Trade/Device Name: JJ Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 1, 2019
Received: November 4, 2019

Dear Kevin Thomas:

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)*

K190552

Device Name

JJ Implant System

Indications for Use *(Describe)*

JJ Implant System Genesis Active implants and Genesis Normo implants are indicated for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations for functional and esthetic rehabilitation. JJ Implant System Genesis Active implants and Genesis Normo implants are indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate.

JJ Implant System Mini implants may be used for denture stabilization using multiple implants in the anterior mandible and the anterior maxilla, and are indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K190552
JJ Implant System
JJ Implants
December 5, 2019

ADMINISTRATIVE INFORMATION

Manufacturer Name	JJ Implants IX /214A, Munipara, Kanjirapilly PO Chalakudy, Kerala, India 680721 Telephone +91 984 600 8283 Fax +91 480 274 6353
Official Contact	Dr. Jiju John, Managing Director
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	JJ Implant System
Common Name	Dental implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Classification Panel	Dental Products Panel
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT & Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate
K142260, Nobel Active®, Nobel Biocare USA, LLC

Reference Devices
K120414, OsseoSpeed™ Plus, Astra Tech AB
K100932, Inclusive Mini Implant, Prismatik Dentalcraft, Incorporated

INDICATIONS FOR USE STATEMENT

JJ Implant System Genesis Active implants and Genesis Normo implants are indicated for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations for functional and esthetic rehabilitation. JJ Implant System Genesis Active implants and Genesis Normo implants are indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate.

JJ Implant System Mini implants may be used for denture stabilization using multiple implants in the anterior mandible and the anterior maxilla, and are indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate.

SUBJECT DEVICE DESCRIPTION

The JJ Implant System comprises three lines of endosseous root-form dental implants: two lines with an internal hexagonal prosthetic interface (Genesis Active and Genesis Normo), mating abutments, abutment screws, and other associated components; and a line of one-piece, small diameter dental implants (Mini) for retention of overdentures. The implant body diameters, platform diameters, and lengths are summarized in the following table.

Implant Line	Body diameter, mm	Platform diameter, mm	Length, mm
Genesis Active	3.0	3.0	8, 10, 11.5, 13
	3.5	3.5	8, 10, 11.5, 13, 16
	3.75	3.5	8, 10, 11.5, 13, 16
	4.2	3.5	8, 10, 11.5, 13, 16
	5.0	3.5	8, 10, 11.5, 13
Genesis Normo	3.2	3.2	8, 10, 11.5, 13
	3.7	3.7	8, 10, 11.5, 13, 16
	4.2	3.7	8, 10, 11.5, 13, 16
	4.7	4.7	8, 10, 11.5, 13
	5.2	4.7	8, 10, 11.5
Mini	2.2	2.5	10, 11.5, 13, 15

Abutment designs for Genesis Active implants include cover screws, healing abutments, straight abutments, angled abutments (15°), and ball attachment abutments in two platform diameters. Abutment designs for Genesis Normo implants include cover screws, healing abutments, straight abutments, and angled abutments (15°) in three platform diameters. The one-piece Mini implant includes an integral ball attachment for denture retention.

JJ Implant System implants, abutments, and abutment screws are manufactured from Ti-6Al-4V alloy conforming to ASTM F136. All implants are provided sterilized by gamma irradiation; all other components are provided non-sterile to the end user.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: sterilization validation according to ISO 11137-1, ISO 11137-2, ISO 17665-1, and ISO 14937; bacterial endotoxin testing according to USP 40-NF 35 <85>; biocompatibility according to ISO 10993-5 and ISO 10993-12; accelerated aging according to ASTM F1980; and static compression and compression fatigue testing according to ISO 14801. Scanning electron microscopy (SEM), energy dispersive X-ray spectroscopy (EDS), and Auger electron spectroscopy were performed on the RBM grit-blasted threaded surface to

evaluate residual materials from the blasting or cleaning operations present on the final devices. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

The Indications for Use Statement (IFUS) for the subject device (the portion of the IFUS for the Genesis Active implants and Genesis Normo implants) is substantially equivalent to that of the primary predicate K142260. Slight differences in the language of the subject device and primary predicate device IFUS do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function. Minor differences between the IFUS for the subject device and the primary predicate include the specific language in the primary predicate device IFUS concerning splinted and non-splinted applications and delayed loading. These minor differences do not impact substantial equivalence because both IFUS express equivalent intended use to facilitate dental prosthetic restorations, and are expressed equivalently using different specific wording.

Similarly, the differences between the subject device IFUS (the portion of the IFUS for the Genesis Active implants and Genesis Normo implants) and that of the reference devices are related to the specific device names, design features, and use of the devices. None of these minor differences impact substantial equivalence because all IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

The IFUS for the subject device (the portion of the IFUS for the Mini implants) is substantially equivalent to that of the reference device K100932 in terms of stabilization of dentures and immediate loading with primary stability and appropriate loading. The minor differences in the specific wording and do not impact substantial equivalence because the IFUS express equivalent intended use and the indications are expressed equivalently using different specific wording.

The subject Genesis Active implant designs are substantially equivalent to those of the primary predicate K142260 in terms of endosseous thread form designs, prosthesis attachment (cement-retained or screw-retained), restorations (single-unit or multi-unit), abutment-implant interface (internal hexagonal connection), material, and sterilization. The ranges of dimensions of body diameter, endosseous length, and platform diameter for the subject Genesis Active implants are within the corresponding ranges of the dimensions of the primary predicate K142260 or of the reference device K120414.

The reference device K120414 is for support of substantial equivalence of the subject Genesis Normo implant designs and for support of substantial equivalence of the subject abutment designs. The subject Genesis Normo implants and the reference device K120414 implants also are substantially equivalent in terms of endosseous thread form designs, prosthesis attachment (cement-retained or screw-retained), restorations (single-unit or multi-unit), abutment-implant interface (internal connection), material, and sterilization. The ranges of dimensions of body diameter, endosseous length, and platform diameter for the subject Genesis Normo implants are within the corresponding ranges of the reference device K120414.

The subject abutment designs also are substantially equivalent to the abutment designs of the reference device K120414. The subject device and the reference device K120414 both include cover screws, healing abutments, straight abutments, angled abutments, and ball attachment abutments. The ranges of dimensions of platform diameter, gingival height, and angulation for the subject abutments are within the corresponding ranges of the reference device K120414. The subject abutments and the reference device K120414 abutments also are substantially equivalent in terms of prosthesis attachment (cement-retained, screw-retained, ball attachment), restorations (single-unit or multi-unit), abutment-implant interface (internal connection), material, and sterilization (by the end user).

The reference device K100932 is for support of substantial equivalence of the subject Mini implant designs. The ranges of dimensions (body diameter and length) for the subject Mini implants are within the corresponding ranges of the reference device K100932. The subject device Mini implants are provided in a body diameter of 2.2 mm in lengths of 10, 11.5, 13, and 15 mm; the reference device K100932 implants are provided in body diameters of 2.2, 2.5, and 3 mm, and each body diameter is provided in lengths of 10, 13, and 15 mm. The subject Mini implants and the reference device K100932 implants also are substantially equivalent in terms of endosseous thread form design, prosthesis attachment (ball attachment), retention of dentures, material, and sterilization.

The subject device abutments and abutment screws are to be moist heat (steam) sterilized by the end-user, the same as the primary predicate K142260 and the reference device K120414.

Confirmatory biocompatibility testing of the subject device was performed according to ISO 10993-5 and ISO 10993-12.

Mechanical performance testing was performed according to ISO 14801. For both Genesis Active implants and Genesis Normo implants (each in combinations with a 15° angled abutment) the testing results demonstrated that the subject device implants have sufficient strength for their intended use.

Minor differences in the designs, dimensions, or sizes among the subject device, the primary predicate device, and the reference devices do not affect substantial equivalence. These minor differences do not impact substantial equivalence because these differences are related to the specific designs of the primary predicate or reference devices.

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device, the primary predicate, and reference devices encompass the same range of physical dimensions, are packaged in similar materials, and are to be sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Comparison of Indications for Use Statements

Subject Device	Primary Predicate	Reference Device	Reference Device
K190552 JJ Implant System JJ Implants	K142260 Nobel Active® Nobel Biocare USA, LLC	K120414 OsseoSpeed™ Plus Astra Tech AB	K100932 Inclusive Mini Implant Prismatik Dentalcraft, Incorporated
JJ Implant System Genesis Active implants and Genesis Normo implants are indicated for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations for functional and esthetic rehabilitation. JJ Implant System Genesis Active implants and Genesis Normo implants are indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate. JJ Implant System Mini implants may be used for denture stabilization using multiple implants in the anterior mandible and the anterior maxilla, and are indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate.	NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive® 3.0 implants are indicated for single unit restorations only.	Implants: The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing single and multiple missing teeth in the mandible and maxilla, • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, • especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective, • immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. The intended use for OsseoSpeed™ Plus 3 .OS is limited to replacement of maxillary lateral incisors and mandibular incisors. Abutments: Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures. Atlantis Abutments: The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.	Inclusive Mini Implants are self-tapping threaded titanium screws indicated for long-term applications. Inclusive Mini Implants may also be used for provisional applications. These devices will allow immediate loading and long-term stabilization of dentures and provisional stabilization of dentures while standard implants heal. To be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

Comparison of Technological Characteristics

Comparison	Subject Device		Primary Predicate	Reference Device	Reference Device
	K190552 JJ Implant System JJ Implants		K142260 Nobel Active® Nobel Biocare USA, LLC	K120414 OsseoSpeed™ Plus Astra Tech AB	K100932 Inclusive Mini Implant Prismatik Dentalcraft, Incorporated
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla and mandible		Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible
Reason for Predicate/ Reference Device	Not applicable		Predicate for subject Genesis Active implant design	Reference for subject Genesis Normo implant design; Reference for subject abutment designs	Reference device for subject Mini implant design
Product Codes	DZE, NHA		DZE, NHA	DZE	DZE
Implant Designs					
Implant Body Diameter (Ø), mm	Genesis Active:	3.0, 3.5, 3.75, 4.2, 5.0	3.0, 3.5, 4.3, 5.0, 5.5		
	Genesis Normo:	3.2, 3.7, 4.2, 4.7, 5.2		3.0, 3.6, 4.2, 4.8, 5.4	
	Mini:	2.2			2.2, 2.5, 3.0
Implant Endosseous Length, mm	Genesis Active:	6 – 16 (varies by body Ø)	6.5 – 18 (varies by body Ø)		
	Genesis Normo:	8 – 16 (varies by body Ø)		6 – 17	
	Mini:	10, 11.5, 13, 15			10, 13, 15
Platform Ø, mm	Genesis Active:	3.0, 3.5 (varies by body Ø)	3.0, 3.5 (NP), 3.9 (RP), 5.1 (WP)		
	Genesis Normo:	3.2, 3.7, 4.7 (varies by body Ø)		3.0, 3.6, 4.2, 4.8, 5.4	
	Mini:	Not applicable			Not applicable
Threads	Genesis Active:	Double-lead, square thread form	Square thread form		
	Genesis Normo:	Micro-thread at coronal aspect; Single-lead thread form to the apex		Micro-thread at coronal aspect; single lead thread form to the apex	
	Mini:	Single-lead thread form to the apex; Self-tapping			Self-tapping
Abutment Designs					
Cover Screws	Genesis Active:	3.0, 3.5 mm coronal Ø (varies by body Ø)		Cover Screw Plus 3.0, 3.6, 4.2, 4.8, 5.4 (to match implant platform Ø)	
	Genesis Normo:	3.2, 3.7, 4.7 mm coronal Ø (varies by body Ø)			
	Mini:	Not applicable			
Healing Abutments	Genesis Active:	4.5, 4.7 mm coronal Ø; 2-6 mm gingival height (GH) (varies by body Ø)		HealDesign Plus 3.0, 3.6, 4.2, 4.8, 5.4 (to match implant platform Ø)	
	Genesis Normo:	3.7, 4.7, 5.7 mm coronal Ø; 3 mm, 5 mm GH			
	Mini:	Not applicable			
Straight Abutments	Genesis Active:	Engaging, 1-4 mm GH (varies by body Ø)		TiDesign Plus 3.0, 3.6, 4.2, 4.8, 5.4 (to match implant platform Ø)	Straight only; one-piece implant with integral ball-attachment connection
	Genesis Normo:	Engaging, 1-3 mm GH			
	Mini:	Straight only; one-piece implant with integral ball-attachment connection			

Comparison of Technological Characteristics

Comparison	Subject Device K190552 JJ Implant System JJ Implants	Primary Predicate K142260 Nobel Active® Nobel Biocare USA, LLC	Reference Device K120414 OsseoSpeed™ Plus Astra Tech AB	Reference Device K100932 Inclusive Mini Implant Prismatik Dentalcraft, Incorporated
Angled Abutments	Genesis Active: Angled 15°, engaging, 1.25-3 mm GH (varies by body Ø) Genesis Normo: Angled 15°, engaging, 1-4.5 mm GH (varies by body Ø) Mini: Not applicable (straight only)		Angled TiDesign Plus Angled 15°, 20°	Not applicable (straight only)
Other	Genesis Active: Ball attachments, 0.5-5 mm GH (varies by body Ø) Genesis Normo: Not applicable Mini: Not applicable (straight only)		Ball Abutment Plus 3.6, 4.2, 4.8, 5.4 (to match implant platform Ø) each with 1-7 mm GH	Not applicable (straight only)
Prosthesis Attachment	Genesis Active: Cement-retained, screw-retained Genesis Normo: Cement-retained, screw-retained Mini: One-piece implant with integral ball-attachment connection	Cement-retained, screw-retained	Cement-retained, screw-retained, ball attachment	One-piece implant with integral ball-attachment connection
Restoration	Genesis Active: Single-unit, multi-unit Genesis Normo: Single-unit, multi-unit Mini: Multi-unit (denture)	Single-unit, multi-unit	Single-unit, multi-unit	Multi-unit (denture)
Abutment/ Implant Interface	Genesis Active: Internal hexagon Genesis Normo: Internal hexagon Mini: Not applicable	Internal hexagon	Internal connection with anti-rotation feature	Not applicable
Materials				
Implants	Ti-6Al-4V alloy, with RBM threaded surface	CP titanium, with TiUnite surface	Unalloyed titanium; OsseoSpeed surface	Ti-6Al-4V alloy, with blasted and etched threaded surface
Abutments	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy, Zirconia, Gold, PEEK	Not applicable
Abutment Screws	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Not applicable
Sterilization Status/Method				
Implants	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile *(process not stated in 510(k) Summary)*
Abutments	Non-sterile; to be moist heat (steam) sterilized	Sterile by gamma irradiation; and Non-sterile; to be moist heat (steam) sterilized	Sterile by gamma irradiation; and Non-sterile; to be moist heat (steam) or dry heat sterilized	Not applicable
Other Components	Non-sterile; to be moist heat (steam) sterilized	Non-sterile; to be moist heat (steam) sterilized	Non-sterile; to be moist heat (steam) sterilized	Not applicable