September 15, 2022

Talladium Espana, SL
% Kevin Thomas
Vice President & Director of Regulatory Affairs
PaxMed International, LLC
12264 EL Camino Real, Suite 400
San Diego, California 92130

Re: K221966
Trade/Device Name: Dynamic TiBase
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 30, 2022
Received: July 5, 2022

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,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Dynamic TiBase

Indications for Use *(Describe)*

Dynamic TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

Implant Compatibility	Implant Body Diameter, mm	Implant Platform, mm
Kontact™ Dental Implant System	3.6	3.6
	4.2	4.2
	4.8	4.8
	5.4	5.4

All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Talladium validated milling center for manufacture.

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.

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510(k) Summary
K221966
Talladium España, SL
Dynamic TiBase

September 14, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Talladium España, SL Virginia Woolf, 17 Lleida, Lleida, ES 25005 Telephone +34 973-289-580
Official Contact	Xavier Soca Filella, General Manager
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	Dynamic TiBase
Common Names	Endosseous dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental and ENT Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K212108, Dynamic TiBase, Talladium España, SL

Reference Device
K210220, Kontact™ Dental Implant System, Biotech Dental, SAS

INDICATIONS FOR USE STATEMENT

Dynamic TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

Implant Compatibility	Implant Body Diameter, mm	Implant Platform, mm
Kontact™ Dental Implant System	3.6	3.6
	4.2	4.2
	4.8	4.8
	5.4	5.4

All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Talladium validated milling center for manufacture.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for Dynamic TiBase, two-piece titanium base abutments that require the fabrication of patient-specific custom zirconia superstructures using CAD-CAM technology. In final, finished form, the subject device abutments are intended to be used as a two-piece abutment composed of the base bottom-half (titanium base) with a bonded CAD-CAM zirconia top-half. Each patient-specific zirconia superstructure is individually prescribed by the clinician and manufactured by an authorized milling center.

The subject device abutments are compatible with Kontact™ Dental Implant System implants manufactured by Biotech Dental, SAS, cleared in K210220 in the following sizes:

- 3.6 mm body diameter/3.6 mm platform;
- 4.2 mm body diameter/4.2 mm platform;
- 4.8 mm body diameter/4.8 mm platform; and
- 5.4 mm body diameter/5.4 mm platform.

The compatibility between the subject device and the Kontact™ Dental Implant System implants was established by a business agreement between Talladium España, SL and Biotech Dental, SAS.

All subject device abutments and abutment screws are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136 and ISO 5832-3.

All Dynamic TiBase abutments are provided in a straight design (no angulation in the TiBase portion) with an engaging implant connection (for crowns), with a gingival height ranging from 1 mm to 3 mm; additional gingival height may be provided in the zirconia superstructure as described below. All Dynamic TiBase abutments are provided with a cut-out in the prosthetic post to accommodate a restoration with an angled screw channel when clinically necessary. The prosthetic post heights are 4.5 mm (maximum height) / 2.5 mm (cutout height) or 4.0 mm/2.5 mm. Dynamic TiBase abutments with a 4.5 mm post height may be shortened to no less than 4 mm for a single-unit restoration.

All zirconia copings (superstructures) for use with the subject device Dynamic TiBase will be made at a Talladium validated milling center under FDA quality system regulations, and the material will conform to ISO 13356.

The design parameters for the CAD-CAM zirconia superstructure for the Dynamic TiBases are:

Minimum wall thickness – 0.55 mm
Minimum post height for single-unit restorations – 4.0 mm
Maximum gingival height – 5.37 mm (in the zirconia superstructure)
Minimum gingival height – 1.0 mm (in the TiBase)
Maximum angulation – 30°

The recommended cement for bonding the zirconia superstructure to the Dynamic TiBases to create the final two-piece abutment is G-CEM LinkAce™, cleared as GAM-200 in K120243.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included: biocompatibility testing according to ISO 10993-5 and ISO 10993-12 (referenced from K212108); moist heat sterilization validation according to ISO 17665-1 and ISO 11737-2 (referenced from K212108); and static compression and compression fatigue testing according to ISO 14801 of worst-case constructs comprising the subject device abutments, zirconia superstructures made to the limits listed above, the subject device abutment screw, and compatible Biotech Dental Kontact™ Dental Implant System implants.

Non-clinical analysis also was performed to evaluate the subject devices (including all abutments, abutment screw, and materials) in the MR environment using scientific rationale and published literature (TO Woods, JG Delfino, and S Rajan, *"Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices," Journal of Testing and Evaluation*, Volume 49, No. 2, 2021, pp. 783-795); the analysis addressed parameters per the FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (issued May 2021) including magnetically induced displacement force and torque.

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 device listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference device.

The primary predicate device K212108 is for support of substantial equivalence of the Indications for Use statement, the abutment designs, materials, manufacturing, sterilization, biocompatibility, and mechanical performance testing.

The reference device K210220 is for support of substantial equivalence of the identical Kontact™ Dental Implant System (Biotech Dental, SAS) implant interface connections and platforms.

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference device 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 device.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate device K212108. Except for the list of compatible OEM implants and the specific required

validated milling centers, the IFUS for the subject device is identical to the IFUS for the primary predicate device K212108.

The subject device abutments have interface connections and platforms that are identical to the compatible Biotech Dental, SAS Kontact™ implant interface connections and platforms cleared in the reference device K210220. The subject device includes designs that are compatible with Biotech Dental Kontact™ implant body/platform diameters of 3.6 mm, 4.2 mm, 4.8 mm, and 5.4 mm. These Kontact™ implant sizes all have the same internal taper connection; therefore, each subject device abutment will fit any of these implant sizes.

The subject device abutments are substantially equivalent in material and design to the abutments in the primary predicate device K212108. The final finished device for both the subject device abutments and the titanium base abutments cleared in K212108 is intended to be used as a two-piece abutment composed of the base bottom-half (titanium base) bonded to a CAD-CAM zirconia top-half.

The subject device abutments are provided with abutment-implant platform diameters that match exactly the reference device K210220, and prosthetic platform diameters that are substantially equivalent to those of the corresponding abutments in K212108 and K210220. Minor differences in the design parameters for zirconia superstructures to be used with the subject device base abutments compared to zirconia superstructures to be used with the predicate device base abutments (minimum wall thickness, maximum gingival height, maximum angulation) are mitigated by mechanical testing of the subject device performed in conformance with ISO 14801.

The subject device includes abutments made of titanium alloy conforming to ASTM F136 and ISO 5832-3. The titanium alloy subject device components are manufactured from identical materials, in the identical facilities using the identical manufacturing processes as used for Talladium España, SL products cleared previously in K212108. In addition, subject device titanium alloy abutments and abutment screw are anodized using a process that is identical to the anodization process used for Talladium España, SL products cleared previously in K212108.

The subject device abutments are to be used with superstructures fabricated from zirconia conforming to ISO 13356; this is the same material used for superstructures in the primary predicate device K212108. Provided as part of the K212108 submission was confirmatory biocompatibility testing for finished subject devices made from titanium alloy with cemented zirconia superstructures performed according to ISO 19003-5 and ISO 10993-12.

Mechanical performance testing of the subject device was performed in conformance to ISO 14801. The fatigue limit data demonstrated that constructs of the subject device abutments fabricated to the limits stated in the proposed labeling, in combination with previously-cleared compatible Biotech Dental, SAS Kontact™ Dental Implant System implants, have sufficient strength for their intended use.

All subject device abutments and all abutments cleared in the primary predicate device K212108 are provided non-sterile and are to be moist heat sterilized by the end user.

Minor differences in the designs, dimensions, sizes, or compatible implant lines between the subject device and the primary predicate device do not affect substantial equivalence. These minor differences do not impact safety or effectiveness because these differences are related to the compatible implant designs and are mitigated by the mechanical performance testing.

CONCLUSION

The subject device, the primary predicate device, and the reference device have the same intended use, have similar technological characteristics, and are made of identical or similar materials. The subject device and the primary predicate device encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate device listed above.

Table of Substantial Equivalence – Indications for Use Statements

<table>
<tr><th>Device</th><th>Indications for Use Statements</th></tr>
<tr><td>Subject Device

Dynamic TiBase
Talladium España, SL</td><td>Dynamic TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

<table><tr><th>Implant Compatibility</th><th>Implant Body Diameter, mm</th><th>Implant Platform, mm</th></tr><tr><td rowspan="4">Kontact™ Dental Implant System</td><td>3.6</td><td>3.6</td></tr><tr><td>4.2</td><td>4.2</td></tr><tr><td>4.8</td><td>4.8</td></tr><tr><td>5.4</td><td>5.4</td></tr></table>
All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Talladium validated milling center for manufacture.</td></tr>
<tr><td>Primary Predicate Device</td><td></td></tr>
<tr><td>K212108
Dynamic TiBase
Talladium España, SL</td><td>Dynamic TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.

<table><tr><th>Implant Compatibility</th><th>Implant Body Diameter, mm</th><th>Implant Platform, mm</th></tr><tr><td rowspan="4">SPI® CONTACT Dental Implant</td><td>2.7</td><td>3.5</td></tr><tr><td>3.5</td><td>4.0</td></tr><tr><td>3.5</td><td>4.5</td></tr><tr><td>4.2</td><td>5.0</td></tr></table>
All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Thommen Medical validated milling center for manufacture.</td></tr>
<tr><td>Reference Device</td><td></td></tr>
<tr><td>K210220
Kontact™ Dental Implant System
Biotech Dental, SAS</td><td>Kontact™ Dental Implant System is indicated for use in partially or fully edentulous patients to support maxillary or mandibular single unit, multiple-unit, or overdenture dental restorations.
Kontact Dental Implant System is indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate.
Kontact 3 mm diameter implants and prosthetics components are indicated for use in surgical and restorative applications in the maxillary lateral incisor or mandibular incisor regions.</td></tr>
</table>

Table of Substantial Equivalence – Technological Characteristics

Features	Subject Device	Primary Predicate Device	Reference Device
		K212108	**K210220**
	Dynamic TiBase	**Dynamic TiBase**	**Kontact™ Dental Implant System**
	Talladium España, SL	**Talladium España, SL**	**Biotech Dental, SAS**
Reason for Predicate Device / Reference Device	**Not applicable**	**Designs, materials, manufacturing, sterilization, biocompatibility, Mechanical performance testing**	**Compatible identical implant interface and platforms**
Product Codes	NHA	NHA	DZE, NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Designs/Features			
Abutment Design	CAD-CAM Titanium Base Abutments	CAD-CAM Titanium Base Abutments	
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	
Abutment-Implant Interface	Internal	Internal	Internal
Abutment-Implant Platform Diameter	3.6 mm, 4.2 mm, 4.8 mm, 5.4 mm	3.5 mm, 4.0 mm, 4.5 mm, 5.0 mm	3.6 mm, 4.2 mm, 4.8 mm, 5.4 mm For these Kontact™ implants, the abutment platform diameter is the same as the implant body diameter, and these implant sizes have the same internal connection geometry.
Prosthetic Platform Diameter	4.0 mm, 4.5 mm	4.1 mm, 4.3 mm, 4.75 mm, 5.25 mm	
Prosthetic Post Height	4.0 mm (maximum) / 2.4 mm (cut-down) 4.5 mm (maximum) / 2.5 mm (cut-down)	4.0 mm (maximum) / 2.3 mm (cut-down) 4.5 mm (maximum) / 3.5 mm (cut-down)	
Zirconia Superstructure Design Parameters			
Minimum wall thickness	0.55 mm	0.34 mm	
Minimum post height for single-unit restorations	4.0 mm	4.0 mm	
Minimum gingival height (GH) of the superstructure	0 mm All bases have minimum GH of 1 mm	0 mm All bases have GH of 0.7 mm	
Maximum gingival height (of the superstructure)	5.37 mm	5.83 mm	
Angulation of Finished Abutment	Up to 30°	Up to 30°	
Cement to bond zirconia superstructure to the abutment base	G-CEM LinkAce™ (cleared as GAM-200 in K120243)	G-CEM LinkAce™ (cleared as GAM-200 in K120243)	
Materials			
Abutments	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	
Superstructures	Zirconia, ISO 13356	Zirconia, ISO 13356	
Abutment Screws	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	