November 17, 2023

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

Re: K231559
Trade/Device Name: Multi-Unit DAS System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 20, 2023
Received: October 20, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sherrill Lathrop Blitzer

for Andrew 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)*
K231559

Device Name

Multi-Unit DAS System

Indications for Use (Describe)

Multi-Unit DAS System 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.

Compatible Implant Systems

Implant Compatibility	Implant Body Diameter, mm	Implant Platform, mm
Astra Tech OsseoSpeed TX	3.5	3.5/4.0
	4.0	3.5/4.0
Biomet 3i OSSEOTITE® Certain®	3.25	3.4
	4.0	4.1
MegaGen AnyRidge	3.5, 4.0, 4.4, 4.9, 5.4	3.5
NobelActive®	3.5	3.5 (NP)
	4.3, 5.0	3.9 (RP)
Zimmer Tapered Screw-Vent®	3.7, 4.1	3.5

All digitally designed custom abutments for use with Multi-Unit DAS System 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
K231559
Talladium España, SL
Multi-Unit DAS System

November 16, 2023

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	Multi-Unit DAS System
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 Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K221966, Dynamic TiBase, Talladium España, SL

Reference Devices
K230143, DESS® Dental Smart Solutions, Terrats Medical SL
K220200, Paltop Conical Implant System, Paltop Advanced Dental Solutions, Ltd
K101732, Astra Tech Implant System, Astra Tech AB
K063341, 3i OSSEOTITE® Certain® Dental Implants, Implant Innovations, Inc.
K140091, Xpeed AnyRidge Internal Implant System, MegaGen Implant Company, Ltd.
K110955, AnyRidge Internal Implant System, MegaGen Implant Company, Ltd.

K142260, NobelActive®, Nobel Biocare AB
K013227, Screw Vent Implant; Tapered Screw Vent Implant, Sulzer Dental, Inc.
K072589, Tapered Screw-Vent Implant, 4.1mmD, Zimmer Dental, Inc.

INDICATIONS FOR USE STATEMENT

Multi-Unit DAS System 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.

Compatible Implant Systems

Implant Compatibility	Implant Body Diameter, mm	Implant Platform, mm
Astra Tech OsseoSpeed TX	3.5	3.5/4.0
	4.0	3.5/4.0
Biomet 3i OSSEOTITE® Certain®	3.25	3.4
	4.0	4.1
MegaGen AnyRidge	3.5, 4.0, 4.4, 4.9, 5.4	3.5
NobelActive®	3.5	3.5 (NP)
	4.3, 5.0	3.9 (RP)
Zimmer Tapered Screw-Vent®	3.7, 4.1	3.5

All digitally designed custom abutments for use with Multi-Unit DAS System abutments are to be sent to a Talladium validated milling center for manufacture.

SUBJECT DEVICE DESCRIPTION

Multi-Unit DAS System abutments are designed for retention of single-unit and multi-unit restorations. The multi-unit abutments are provided in a straight design (no angulation in the base portion) that threads directly to the OEM implant. For each of the compatible OEM implant lines, the multi-unit abutments are provided with gingival heights ranging from 1 mm to 5 mm, a prosthetic platform diameter of 4 mm, and a prosthetic post height of 1.4 mm. The multi-unit abutments are the base of a two-piece abutment. The second piece is a metal coping, called a Ti-Base in this submission, that attaches to the multi-unit abutment (not directly to an implant). For permanent restorations a zirconia superstructure is attached to the Ti-Base, and additional gingival height and angulation may be provided in the zirconia superstructure.

The subject device metal copings (Ti-Bases) include: a straight, prepable design with an additional gingival height of 1.5 mm and a prepable 9 mm prosthetic post; and Dynamic Ti-Bases in three (3) designs, each with an additional gingival height of 0.5 mm and a cut-out in the prosthetic post to accommodate a restoration with an angled screw channel when clinically necessary. The Dynamic Ti-Base prosthetic post heights are 4.5 mm (maximum height) / 3.0 mm (cut-out height), and 9.0 mm/3.5 mm. Multi-Unit DAS System Ti-Bases with a 9.0 mm post height may be shortened to no less than 4 mm for a single-unit restoration. The prepable Ti-Base has a platform diameter of 4 mm (platform to the multi-unit abutment) and a prosthetic platform diameter of 4 mm. The Dynamic Ti-Bases have a platform diameter of 4 mm (platform to the multi-unit abutment) and a prosthetic platform diameter of 4.15 mm.

The compatibility between the subject device abutments and the OEM implants listed in the Indication for Use Statement was established by reverse engineering analysis of the OEM implants, OEM abutments, and OEM abutment screws.
All subject device abutments and abutment screws are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136 and ISO 5832-3.

All zirconia copings (superstructures) for use with the subject device Dynamic Ti-Base will be made at a Talladium España, SL 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 Multi-Unit DAS System are:

Minimum wall thickness – 0.25 mm

Minimum post height for single-unit restorations – 4.0 mm

Maximum gingival height in the zirconia superstructure – 5.24 mm for compatible Biomet 3i OSSEOTITE® Certain®, MegaGen AnyRidge, NobelActive®, and Zimmer Tapered Screw-Vent® implants; 5.76 mm for compatible Astra Tech OsseoSpeed TX implants

Minimum gingival height – 0.5 mm (in the Ti-Base)

Maximum angulation – 30° for compatible Biomet 3i OSSEOTITE® Certain®, MegaGen AnyRidge, NobelActive®, and Zimmer Tapered Screw-Vent® implants; 25° for compatible Astra Tech OsseoSpeed TX implants

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 or referenced to demonstrate substantial equivalence included:

- provided in this submission was moist heat sterilization for subject devices provided non-sterile to the end user, validated to a sterility assurance level of 10^{-6} by the overkill method according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO TIR 17665-2;
- provided in this submission was reverse engineering analysis (of OEM implants, OEM abutments, and OEM abutment screws) demonstrating compatibility between the subject device abutments and the OEM implants listed in the Indication for Use Statement;
- provided in this submission was mechanical testing conducted according to ISO 14801 to support the performance of the subject device abutments in conjunction with the compatible OEM implants;
- referenced from K221966 (provided in K212108) was biocompatibility testing according to ISO 10993-5 (cytotoxicity) covering the finished subject devices manufactured from titanium alloy (ASTM F136) with cemented zirconia superstructures (ISO 13356); and
- 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 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 K221966, and the reference device K230143.

The primary predicate device K221966 is for support of substantial equivalence in terms of abutment designs, materials, manufacturing, biocompatibility, and sterilization. The reference device K230143 is for support of substantial equivalence in terms of abutment designs. The reference devices K101732, K063341, K140091, K110955, K142260, K013227, and K072589 are for the OEM implant sizes.
The subject device abutments are substantially equivalent in intended use to the abutments cleared in primary predicate device K221966 and the reference device K230143. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation. The Indications for Use Statement (IFUS) for the subject device is identical to that of the primary predicate device K221966 except for the marketing names and the list of compatible OEM implants. The IFUS for the subject device also is similar to that of the reference device K230143 except for the marketing names and the list of compatible OEM implants.

All subject device multi-unit abutments are similar in design, materials, and technological characteristics to the multi-unit abutments cleared in the primary predicate device K221966 and the reference device K230143. The subject device and the reference device K220200 include multi-part abutments (finished device comprising a non-engaging multi-unit abutment, a metal coping, and a zirconia superstructure) for single-unit restorations.

The subject device abutments and prosthetic components are manufactured from identical materials, in the identical facilities using the identical manufacturing processes as used for Talladium España, SL abutments and abutment screws previously cleared in the primary predicate device K221966.

The subject device multi-unit abutments and the multi-unit abutments in the reference device K230143 have similar or identical ranges of implant-abutment platform diameter, prosthetic platform diameter, and gingival height.

The subject device Ti-Base components are to be used with a zirconia superstructure with similar design parameters as the primary predicate K221966. The zirconia material and recommended cement to bond the superstructure to the prosthetic component is the same as the primary predicate K221966.

All abutment screws are similar in design, materials, and technological characteristics to those cleared in the primary predicate device K221966, except for the threads and lengths.

Subject device components that are provided non-sterile are to be sterilized by the same moist heat cycle as in the primary predicate K221966. The subject devices are provided in pouches manufactured from a polyethylene terephthalate (PET) and cast polypropylene (CPP) laminate, identical to the primary predicate K221966.

The subject device Multi-Unit Abutments are to be used with the subject device Ti-Bases to create the final two-piece abutment. The risks associated with the use of an angled zirconia superstructure bonded to the subject device Ti-Bases attached to the subject device Multi-Unit Abutments were mitigated by mechanical testing performed according to ISO 14801.

Minor differences in the designs, dimensions, sizes, or compatible implant lines among the subject device, the primary predicate device K221966, and the reference device K230143 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.

Substantial Equivalence – Indications for Use Statement

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Subject Device</td><td></td></tr>
<tr><td>K231559
Multi-Unit DAS System
Talladium España, SL</td><td>Multi-Unit DAS System 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.
Compatible Implant Systems
<table>
<tr><th>Implant Compatibility</th><th>Implant Body Diameter, mm</th><th>Implant Platform, mm</th></tr>
<tr><td rowspan="2">Astra Tech OsseoSpeed TX</td><td>3.5</td><td>3.5/4.0</td></tr>
<tr><td>4.0</td><td>3.5/4.0</td></tr>
<tr><td rowspan="2">Biomet 3i OSSEOTITE® Certain®</td><td>3.25</td><td>3.4</td></tr>
<tr><td>4.0</td><td>4.1</td></tr>
<tr><td>MegaGen AnyRidge</td><td>3.5, 4.0, 4.4, 4.9, 5.4</td><td>3.5</td></tr>
<tr><td rowspan="2">NobelActive®</td><td>3.5</td><td>3.5 (NP)</td></tr>
<tr><td>4.3, 5.0</td><td>3.9 (RP)</td></tr>
<tr><td>Zimmer Tapered Screw-Vent®</td><td>3.7, 4.1</td><td>3.5</td></tr>
</table>
All digitally designed custom abutments for use with Multi-Unit DAS System 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>K221966
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>
</table>

Substantial Equivalence – Indications for Use Statement

	Indications for Use Statement
Reference Device	
K231043 Terrats Medical SL DESS® Dental Smart Solutions	DESS Multi-Unit Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

Compatible Implant Systems

Compatible Implant Systems	**Implant Body Ø, mm**	**Implant Platform Ø, mm**
Internal Hex Connection		
Legacy1	3.7	3.5
	4.2	3.5
	4.7	4.5
Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, Legacy4	3.7	3.5
	4.2	3.5
	4.7	4.5
	5.2	4.5
Internal Conical Connection		
InterActive	3.2	3.0
	3.7	3.0
	4.3	3.4
	5.0	3.4
Simply Iconic™	3.2	3.0
	3.7	3.0
	4.2	3.0
	4.7	3.0
	4.7	3.4
	5.2	3.4
	5.7	3.4

Table of Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate Device	Reference Device
	K231559 Multi-Unit DAS System Talladium España, SL	K221966 Dynamic TiBase Talladium España, SL	K231043 Terrats Medical SL DESS® Dental Smart Solutions
Reason for Predicate Device	Not applicable	Abutment designs, materials, manufacturing, biocompatibility, and sterilization	Abutment designs
Product Codes	NHA	NHA	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
Abutment Designs			
Abutment Types	Multi-unit, straight (0°)	CAD-CAM Titanium Base Abutments	Multi-unit, straight (0°), 17°, 30°
Prosthesis Attachment	Screw retained	Cement-retained, screw-retained	Screw retained
Restoration	Multi-unit	Single-unit and multi-unit	Multi-unit
Prosthetic Interface Connections	Internal	Internal	Internal
Implant-Abutment Platform Diameter	3.4 mm – 4.1 mm	3.6 mm – 5.4 mm	3.0 mm – 4.5 mm
Prosthetic Platform Diameter	4.0 mm, Multi-unit Abutments 4.15 mm Ti-Base for Multi-unit Abutments	4.0 mm, 4.5 mm	4.8 mm
Gingival Height	1 mm – 5 mm	1 mm (minimum)	1 mm – 5 mm
Abutment Angulation, degrees	Straight (0°)	Straight (0°)	Straight (0°), 17°, 30°
Zirconia Superstructure Design Parameters			
Minimum wall thickness	0.25 mm	0.55 mm	Not applicable
Minimum post height for single-unit restorations	4.0 mm	4.0 mm	Not applicable
Minimum gingival height (GH) of the superstructure	0 mm; all Ti-Bases have minimum GH 0.5 mm	0 mm; all bases have minimum GH of 1 mm	Not applicable
Maximum gingival height (of the superstructure)	5.24 mm for Biomet 3i OSSEOTITE® Certain®, MegaGen AnyRidge, NobelActive®, and Zimmer Tapered Screw-Vent® implants 5.76 for Astra Tech OsseoSpeed TX implants	5.37 mm	Not applicable
Angulation of Finished Abutment	Up to 30° for Biomet 3i OSSEOTITE® Certain®, MegaGen AnyRidge, NobelActive®, and Zimmer Tapered Screw-Vent® implants Up to 25° for Astra Tech OsseoSpeed TX implants	Up to 30°	Not applicable
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)	Not applicable
Abutment Material	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Ti-6Al-4V ELI
Abutment Screw Material	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Ti-6Al-4V ELI
Superstructure Material	Zirconia, ISO 13356	Zirconia, ISO 13356	Not applicable
How Provided			
Sterilization	Non-sterile	Non-sterile	Non-sterile
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use