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

October 21, 2024

Re: K241170
Trade/Device Name: Dynamic TiBase; TRI Screws
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 26, 2024
Received: September 17, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Andrew I. Steen -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241170

Device Name

Dynamic TiBase; TRI Screws

Indications for Use (Describe)

Dynamic TiBase
Dynamic TiBase abutments are intended for use with dental implants as a support for single-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 Diameter, name (mm)
SGS P1D Conical	5.0	3.5 (3.0 mm)
SGS P7N Narrow Conical	3.2	2.1 (2.5 mm)

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

TRI Screws
TRI Screws are intended to secure TRI-matrix® Crown Abutments to TRI-matrix® implants.

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.

510(k) Summary
K241170
Talladium España, SL
Dynamic TiBase; TRI Screws

October 18, 2024

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 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Dynamic TiBase; TRI Screws
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
K232151, Dynamic TiBase, Talladium España, SL

Reference Devices
K182219, SGS® Dental Implants System, SGS International Ltd.
K203660, TRI-matrix® Implant Line, TRI Dental Implants Int. AG

INDICATIONS FOR USE STATEMENT

Dynamic TiBase
Dynamic TiBase abutments are intended for use with dental implants as a support for single-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 Diameter, name (mm)
SGS P1D Conical	5.0	3.5 (3.0 mm)
SGS P7N Narrow Conical	3.2	2.1 (2.5 mm)

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

TRI Screws
TRI Screws are intended to secure TRI-matrix® Crown Abutments to TRI-matrix® implants.

SUBJECT DEVICE DESCRIPTION

Dynamic TiBase abutments are designed for retention of a CAD-CAM fabricated zirconia superstructure where the final two-piece abutment (base and cemented superstructure) is the finished device used for the prosthetic restoration. All subject device bases are made of titanium alloy (Ti-6Al-4V) conforming to ISO 5832-3 and ASTM F136. The Dynamic TiBase abutments are provided in engaging designs for single-unit restorations.

Dynamic TiBase abutments are provided in sizes compatible with the following SGS® Dental Implants System implants:
SGS P1D, Conical connection, 5.0 mm body diameter, 3.5 (3.0 mm) platform; and
SGS P7N, Narrow Conical connection, 3.2 mm body diameter, 2.1 (2.5 mm) platform.

All Dynamic TiBase abutments are provided in a straight design (no angulation in the TiBase portion). All Dynamic TiBase abutments have a prosthetic post with a cut-out to accommodate a restoration with an angled channel for screw access when clinically necessary.

For the compatible SGS P1D Conical connection implant, the Dynamic TiBase abutments are provided with a gingival height (in the titanium base) of 0.5 mm, 1.5 mm, or 3.0 mm, and a prosthetic platform diameter of 4.3 mm. Angulation and additional gingival height may be provided in the zirconia superstructure. For the compatible SGS P1D Conical connection implant, the abutments have a prosthetic post height (length above the gingival height) of 4.0 mm, and a cut-out height of 2.5 mm.

For the SGS P7N Narrow Conical connection implant, the gingival height (in the titanium base) is 0.5 mm or 1.5 mm, and a prosthetic platform diameter of 3.8 mm. Angulation and additional gingival height may be provided in the zirconia superstructure. For the compatible P7N Narrow Conical connection implant the abutments have a prosthetic post height (length above the gingival height) of 4.5 mm, and a cut-out height of 2.5 mm. Dynamic TiBase abutments with a 4.5 mm maximum post height may be shortened to no less than 4 mm for a single-unit restoration.

A summary of the subject device Dynamic TiBase compatibilities with the OEM implants is provided in the following Table 1 *Summary of the Subject Device Dynamic TiBase Abutments.*

Table 1 – Summary of the Subject Device Dynamic TiBase Abutments

Compatible SGS Dental Implants			**Subject Device Dynamic TiBase Abutments**		
Implant	Body Ø	Platform Ø name (mm)	Gingival Height	TiBase Ø	Prosthetic Post Height (Maximum height/ cut-out height)
SGS P1D Conical	5.0 mm	3.5 (3.0 mm)	0.5, 1.5, 3.0 mm	4.3 mm	4.0 mm / 2.5 mm
SGS P7N Narrow Conical	3.2 mm	2.1 (2.5 mm)	0.5, 1.5 mm	3.8 mm	4.5 mm / 2.5 mm

The compatibility between the subject device abutments and the SGS dental implants has been established on the basis of a contractual agreement and working relationship between SGS International Ltd. and Talladium España, SL to ensure that the subject device abutments and abutment screws are designed to fit the corresponding SGS implants.

All zirconia copings (superstructures) for use with the subject device Dynamic TiBase 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 Dynamic TiBase vary between the compatible implants. The design parameters for the CAD-CAM zirconia superstructure are summarized in the following Table 2 *Summary of the Zirconia Superstructure Design Parameters.*

Table 2 – Summary of the Zirconia Superstructure Design Parameters

Compatible SGS Dental Implants			**Subject Device Dynamic TiBase**	**Zirconia Superstructure**		
Implant	Body Ø	Platform Ø, name (mm)	Gingival Height, mm	Maximum Angulation	Minimum Wall Thickness	Maximum Gingival Height
SGS P1D Conical	5.0 mm	3.5 (3.0 mm)	0.5 mm	25º	0.32 mm	5.0 mm
			1.5 mm	20º		
			3.0 mm	15º		
SGS P7N Narrow Conical	3.2 mm	2.1 (2.5 mm)	0.5 mm	25º	0.30 mm	5.05 mm
			1.5 mm	20º		

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.

The subject device TRI Screws are to be used only to attach TRI-matrix® Crown Abutments to TRI-matrix® implants. The TRI-matrix® Crown Abutments and TRI-matrix® implants are manufactured by TRI Dental Implants Int. AG and were cleared in K203660. The TRI screws have a hexalobular instrument interface, a screw head diameter of 2.6 mm, 1-72 UNF thread, and an overall length of 5.15 mm or 7.6 mm. The TRI Screws are anodized to a gold color and are only intended to be used with straight abutments. The compatible abutments are made from zirconia and are for direct final restorations.

The compatibility between the subject device TRI Screws and the TRI dental implants has been established on the basis of a contractual agreement and working relationship between TRI Dental Implants Int. AG and Talladium España, SL to ensure that the subject device abutment screws are designed to fit the corresponding TRI implants.

PERFORMANCE DATA

Non-clinical data submitted or referenced to demonstrate substantial equivalence included:

- provided in this submission was a non-clinical worst-case MRI review to evaluate the subject device components in the MR environment using scientific rationale and published literature (T.O. Woods, J.G. 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 (March/April 2021): 783–795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition, and the rationale addressed parameters per the FDA guidance document *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (issued October 2023), including magnetically induced displacement force and torque;
- referenced from K232151 (provided in K212108) 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;
- referenced from K232151 (provided in K212108) was biocompatibility testing according to ISO 10993-5 (cytotoxicity) for the abutment materials ASTM F136 and ISO 13356;
- 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.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device abutments and abutment screws are substantially equivalent in intended use to the abutments and abutment screws cleared in the primary predicate device K232151 and to the abutment screws cleared in the reference device K203660. All subject device components are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation. The Dynamic TiBase portion of the Indications for Use Statement (IFUS) for the subject device is identical to that of the primary predicate device K232151 except for the list of the compatible OEM implants. The TRI Screws portion of the subject device IFUS is nearly identical to the last sentence of the IFUS of the reference device K203660.

All subject device titanium base abutments and abutment screws are similar in design, materials, and technological characteristics to the titanium base abutments and abutment screws cleared in the primary predicate device K232151 and to the abutment screws cleared in the reference device K203660. Provided at the end of this attachment are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device K232151, and the reference device K203660.

The subject device abutments and abutment screws 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 K232151. The subject device titanium base abutments and the titanium base abutments in the primary predicate device K232151 have similar or identical ranges of implant-abutment platform diameter, prosthetic platform diameter, and gingival height. The reference device K182219 is for the OEM implant body clearance and substantial equivalence of the implant-abutment platform sizes.

The subject device titanium base abutments are to be used with a zirconia superstructure with similar design parameters as those of the primary predicate K232151. The zirconia material and recommended cement to bond the superstructure to the prosthetic component are the same as those of the primary predicate K232151.

The subject device abutment screws for the compatible SGS® Dental Implants System implants are similar in design, materials, and technological characteristics to the abutment screws cleared in the primary predicate device K232151 (for other OEM implant compatibilities), except for the threads and lengths.

All subject device components are provided non-sterile and are to be sterilized by the same moist heat cycle as in the primary predicate K232151. The subject devices are provided in pouches manufactured from a polyethylene terephthalate (PET) and cast polypropylene (CPP) laminate, identical to the primary predicate K232151.

The subject device titanium base abutments are to be used with a zirconia superstructure to create the final two-piece abutment. The risks associated with the use of an angled zirconia superstructure bonded to the subject device titanium base abutments are mitigated by the mechanical testing according to ISO 14801 provided in this submission.

The subject device abutment screws that are compatible with the TRI-matrix® Implant Line are to be used only with straight abutments. Therefore, mechanical testing for these abutments screws was not required.

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

The basis for the belief of Talladium España, SL that the subject device is substantially equivalent to the predicate device and the reference devices is summarized in the following tables *Substantial Equivalence – Indications for Use Statements* and *Substantial Equivalence – Technological Characteristics*.

Substantial Equivalence – Indications for Use Statements

<table>
<tr><th></th><th>Indications for Use Statements</th></tr>
<tr><td>Subject Device
K241170
Dynamic TiBase
Talladium España, SL</td><td>
Dynamic TiBase
Dynamic TiBase abutments are intended for use with dental implants as a support for single-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 Diameter, name (mm)</th></tr>
<tr><td>SGS P1D Conical</td><td>5.0</td><td>3.5 (3.0 mm)</td></tr>
<tr><td>SGS P7N Narrow Conical</td><td>3.2</td><td>2.1 (2.5 mm)</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.

TRI Screws
TRI Screws are intended to secure TRI-matrix® Crown Abutments to TRI-matrix® implants.
</td></tr>
<tr><td>Primary Predicate Device
K232151
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.

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, 4.0</td><td>3.5/4.0</td></tr>
<tr><td>4.5, 5.0</td><td>4.5/5.0</td></tr>
<tr><td rowspan="2">Biomet 3i OSSEOTITE® Certain®</td><td>4.0</td><td>3.4</td></tr>
<tr><td>4.0, 5.0</td><td>4.1</td></tr>
<tr><td>MegaGen AnyRidge</td><td>4.0, 4.4, 4.9, 5.4</td><td>3.5</td></tr>
<tr><td rowspan="3">Nobel Biocare 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>5.5</td><td>5.1 (WP)</td></tr>
<tr><td rowspan="3">Zimmer Tapered Screw-Vent®</td><td>3.7, 4.1</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td></tr>
<tr><td>6.0</td><td>5.7</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>Reference Device
K203660
TRI-matrix® Implant Line
TRI Dental Implants Int. AG</td><td>
The TRI-matrix® Implant Line is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI-matrix® Implant Line allows for one and two stage surgical procedures. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. TRI-matrix® Implant Line 6.5 mm implants are intended for delayed loading only.

The TRI-matrix® Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the TRI-matrix® Crown Abutment to the endosseous implant.
</td></tr>
</table>

Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Predicate Device
	K241170 Dynamic TiBase Talladium España, SL	K232151 Dynamic TiBase Talladium España, SL
Reason for Predicate Device	Not applicable	IFUS; abutment designs; materials; manufacturing; biocompatibility; sterilization
Product Codes	NHA	NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Abutment Designs		
Abutment Types	CAD-CAM titanium base abutments	CAD-CAM titanium base abutments
Prosthesis Attachment	Cement-retained, screw-retained	Cement-retained, screw-retained
Restoration	Single-unit	Single-unit and multi-unit
Prosthetic Interface Connections	Internal	Internal
Implant-Abutment Platform Diameter	2.5 mm – 3.0 mm	3.4 mm – 5.7 mm
Prosthetic Platform Diameter	3.8 mm – 4.3 mm	4.3 mm – 5.9 mm
Gingival Height (in the TiBase)	0.5 mm – 3 mm	0.3 mm – 5 mm
Abutment Angulation, degrees (in the TiBase)	Straight (0°)	Straight (0°)
Zirconia Superstructure Design Parameters		
Minimum wall thickness	0.30 mm	0.32 mm
Minimum post height (length above the gingival 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 0.5 mm	0 mm; all bases have minimum GH 0.3 mm
Maximum gingival height (of the superstructure)	5.05 mm	5.18 mm
Angulation of Finished Abutment	Up to 25°	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)
Abutment Base Material	Titanium alloy, ASTM F136, ISO 5832-3	Titanium alloy, ASTM F136, ISO 5832-3
Abutment Screw Material	Titanium alloy, ASTM F136, ISO 5832-3	Titanium alloy, ASTM F136, ISO 5832-3
Abutment Screw Instrument Interface	Hexalobular	Hexalobular
Superstructure Material	Zirconia, ISO 13356	Zirconia, ISO 13356
How Provided		
Sterilization	Provided non-sterile; to be moist heat sterilized by the end user	Provided non-sterile; to be moist heat sterilized by the end user
Usage – All Components	Single patient, single use	Single patient, single use