May 30, 2025

Talladium España, SL
℅ Rebecca Kattan
Regulatory Specialist
PaxMed International, LLC
1925 Palomar Oaks Way
Suite 210
Carlsbad, California 92008

Re: K243530
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: November 14, 2024
Received: May 6, 2025

Dear Rebecca Kattan:

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)*

K243530

Device Name

Dynamic TiBase

Indications for Use *(Describe)*

Dynamic TiBase 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 System (Connection)	**Implant Body Diameter, mm**	**Implant Platform, mm**
Osstem® TS Hiossen® ET (Internal Taper)	3.5	Mini
	4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular
Neodent GM (Morse taper)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC
	4.1, 4.8	RC
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB

Compatible Abutment System

Compatible Abutment System (Connection)	**Compatible Abutment Angulation**	**Compatible Abutment Platforms**
Nobel Biocare Multi-Unit Abutment Plus (Conical Connection)	0° only	NP, RP, WP

All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Talladium Medical 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.

510(k) Summary
K243530
Talladium España, SL Dynamic TiBase
May 30, 2025

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	Rebecca E. Kattan, PhD Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 1925 Palomar Oaks Way, Suite 210 Carlsbad, CA 92008 Telephone: +1 858-792-1235 Email: rkattan@paxmed.com kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Dynamic TiBase
Common Name	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
K240208, DESS Dental Smart Solutions, Terrats Medical SL; and
K212108, Dynamic TiBase, Talladium España, SL

Reference Devices for OEM implant body clearances
K112532, ET III Bio-SA Fixture System, HIOSSEN INC.
K161604, OSSTEM Implant System, OSSTEM Implant Co., Ltd.
K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários SA
K180536, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.
K201225, Neodent Implant System – GM Helix Implants 7.0, JJGC Indústria e Comércio de Materiais Dentários S.A.
K142260, NobelActive, Nobel Biocare USA

K161416, Multi-Unit Abutment Plus, Nobel Biocare AB
K140878, Straumann® Bone Level Tapered Implants, Straumann USA, LLC
K173961, Straumann® BLX Implant System, Institut Straumann AG
K181703, Straumann® BLX Line Extension – Implants, SRAs and Anatomic Abutments, Institut Straumann AG
K191256, Straumann BLX Ø3.5 mm Implants, Institut Straumann AG
K210855, Straumann BLX Implant System, Institut Straumann AG
K212533, Straumann BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implant, Institut Straumann AG

The primary predicate device K232151 is for support of substantial equivalence in terms of abutment designs, materials, manufacturing, biocompatibility, and sterilization. The reference device K240208 is for support of substantial equivalence of the range of platform diameters of the subject device. The reference device K212108 is for support of substantial equivalence in terms of biocompatibility of the abutment and screw materials. The reference device K161416 is for the Multi-Unit Abutments compatible with the NobelActive implants cleared in K142260.

INDICATIONS FOR USE STATEMENT

Dynamic TiBase 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 System (Connection)	**Implant Body Diameter, mm**	**Implant Platform, mm**
Osstem® TS Hiossen® ET (Internal Taper)	3.5	Mini
	4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular
Neodent GM (Morse taper)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM
Nobel Active (Conical Connection)	3.5	NP
	4.3, 5.0	RP
	5.5	WP
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC
	4.1, 4.8	RC
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB

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

SUBJECT DEVICE DESCRIPTION

Dynamic TiBase abutments are two-piece abutments composed of a CAD-CAM fabricated zirconia superstructure and a prefabricated titanium base component 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 and non-engaging designs for single-unit and multi-unit restorations, respectively.

For each of the compatible OEM implant lines, the prefabricated titanium base components are provided with a gingival height (in the titanium base) ranging from 0.3 mm to 4 mm, and a platform diameter ranging from 4.30 mm to 5.50 mm. Angulation and additional gingival height may be provided in the zirconia superstructure. All Dynamic TiBase prefabricated titanium base components have a post with a cut-out to accommodate a restoration with an angled channel for screw access when clinically necessary. The post height of the prefabricated titanium base component ranges from 3.8 mm to 5.40 mm, and from 2.3 mm to 3.8 mm (cut-out height). The cementable post height of the final patient-matched abutment design, measured above the total combined gingival collar, shall be no less than 4 mm.

All zirconia superstructures (copings) used to complete the final two-piece subject device Dynamic TiBase abutment 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 slightly among the compatible OEM implants. The design parameters for the CAD-CAM zirconia superstructure are summarized in the following table:

Implant Compatibility [(1)]	**Minimum Wall Thickness, mm**	**Maximum Gingival Height, mm**	**Minimum Gingival Height [(2)], mm**	**Maximum Angulation**
Osstem® TS Hiossen® ET (Internal Taper)	0.32	5.18	1.2	25º
Neodent GM (Morse taper)	0.32	5.20	1.2	30º
Nobel Active (Conical Connection)	0.35	6.20	0.30	0º
Straumann Bone Level (CrossFit® Morse Taper)	0.32	5.18	1.1	30º
Straumann BLX (TorcFit™ Internal Hexalobular)	0.32	5.34	1.5	30º

(1) for the compatible sizes shown in Table 1
(2) minimum gingival height in the titanium base, not the zirconia superstructure

The required cement for bonding the zirconia superstructure to the Dynamic TiBases to create the final two-piece abutment is Nova Resin Cement cleared in K213609.

Also, the subject of this submission are seven (7) abutment screws for use with the subject abutments.

PERFORMANCE DATA

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

- 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 *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, *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; and
- provided in this submission was reverse engineering dimensional analysis (of OEM implant bodies, OEM abutments, and OEM abutment screws) to demonstrate that the subject device abutments are compatible with Osstem® TS/ Hiossen® ET, Neodent GM, NobelActive, Straumann Bone Level, and Straumann BLX Implant Systems.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device abutments are substantially equivalent in intended use to the abutments cleared in primary predicate device K232151 and the reference device K240208. 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 K232151 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 K240208 except for the marketing names and the list of compatible OEM implants.

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 and reference device K212108.

The subject device titanium base abutments and the titanium base abutments in the primary predicate device K232151 and the reference device K240208 have similar or identical ranges of implant-abutment platform diameter, prosthetic platform diameter, and gingival height.

The subject device titanium base abutments are to be used with a zirconia superstructure with similar design parameters as the primary predicate K232151 and reference device K212108. The zirconia material and recommended cement to bond the superstructure to the prosthetic component are the same as the primary predicate K232151 and reference device K212108.

All abutment screws are similar in design, materials, and technological characteristics to those cleared in the primary predicate device K232151 and reference device K212108, except for the threads and lengths.

The subject device components are provided non-sterile and are to be sterilized by the same moist heat cycle as in the primary predicate K232151 and reference device K212108. The subject devices are provided in pouches manufactured from a polyethylene terephthalate (PET) and cast polypropylene (CPP) laminate, identical to the primary predicate K232151 and reference device K212108.

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.

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 *Table of Substantial Equivalence.*

Table of Substantial Equivalence

Comparison / Features	**Subject Device** K243530 Dynamic TiBase Talladium España, SL	**Predicate Device** K232151 Dynamic TiBase Talladium España, SL	**Reference Device** K240208 DESS Dental Smart Solutions Terrats Medical SL
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. *<complete list of OEM compatibile implants is provided in the Indications for Use Statement>* All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Talladium validated milling center for manufacture.	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. *<complete list of OEM compatibile implants is provided in the Indications for Use Statement of K232151>* All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Talladium validated milling center for manufacture.	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. *<complete list of OEM compatibile implants is provided in the Indications for Use Statement of K240208>* All digitally designed custom abutments for use with DESS Ti Base abutments or Pre-Milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture.
Reason for Predicate Device	Not applicable	IFUS; abutment designs; materials; biocompatibility; sterilization	Abutment designs and materials
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	CAD-CAM titanium base abutments	CAD-CAM titanium base abutments	Various types, including CAD-CAM titanium base abutments
Prosthesis Attachment	Cement-retained, screw-retained	Cement-retained, screw-retained	Cement-retained, screw-retained
Restoration	Single-unit, Multi-unit	Single-unit	Single-unit and multi-unit
Prosthetic Interface Connections	Internal	Internal	Internal and external hex
Diameter of prefabricated titanium base component	4.30 mm – 5.5 mm	4.3 mm – 5.9 mm	3.85 mm – 6.0 mm (titanium base abutments)
Gingival Height (in the base)	0.3 mm- 4.0 mm	0.3 mm – 5 mm	0.3 mm – 3.0 mm (titanium base abutments)
Zirconia Superstructure Design Parameters			
Minimum wall thickness	0.20 mm	0.32 mm	0.40 mm
Minimum post height for single unit restorations (post height measured above the gingival height of the final patient-matched design)	4.0 mm	4.0 mm	4.2 mm
Minimum gingival height (GH) of the superstructure	0 mm; all bases have minimum GH 0.3 mm	0 mm; all bases have minimum GH 0.3 mm	0.5 mm
Maximum gingival height (of the superstructure)	6.20 mm	5.18 mm	6.0 mm
Angulation of Finished Abutment	Up to 30°	Up to 30°	Up to 30°
Materials			
Prefabricated titanium base component material	Ti-6Al-4V alloy, ASTM F136, ISO 5832-3	Ti-6Al-4V alloy, ASTM F136, ISO 5832-3	Ti-6Al-4V alloy, ASTM F136, ISO 5832-3
Superstructure Material	Zirconia, ISO 13356	Zirconia, ISO 13356	Zirconia, ISO 13356
Cement to bond zirconia superstructure to the abutment base	Nova Resin Cement (cleared in K213609)	G-CEM LinkAce™ (cleared as GAM-200 in K120243)	Multi-Link cement by Ivoclar Vivadent
Abutment Screw Material	Ti-6Al-4V alloy, ASTM F136, ISO 5832-3	Ti-6Al-4V alloy, ASTM F136, ISO 5832-3	Ti-6Al-4V alloy, ASTM F136, ISO 5832-3
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	Sterile by gamma irradiation, and Non-sterile
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use