August 20, 2025

IMPLANT PROTESIS DENTAL 2004, S.L.
Francesc Fumanal
Regulatory Affairs Manager
Carrer Rosa dels Vents, 9-15.
Premià de Dalt (Barcelona), 08338
SPAIN

Re: K251471
Trade/Device Name: IPD Dental Implant Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: July 22, 2025
Received: July 22, 2025

Dear Francesc Fumanal:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251471 ?
Please provide the device trade name(s). ?	

IPD Dental Implant Abutments

Please provide your Indications for Use below. ?

IPD Dental Implant Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single or multiple dental prosthetic restorations.

Compatible Implant Systems

Compatible System	Implant/Abutment Diameter (mm)	Platform Diameter
OsseoSpeed™ Plus	3.0	3.0
	3.6	3.6
	4.2	4.2
	4.8	4.8
BioHorizons Tapered Internal Implant System	3.0	3.0
	3.4	3.0
	3.8	3.5
	4.6	4.5
	5.8	5.7
Straumann® BLX Implant System	3.5 - 4.5	RB
	5.0 - 6.5	WB
Straumann BLX Ø3.5 mm Implants	3.5	RB
Straumann® Screw-Retained Abutments	3.5	NC
	4.6	RC
Xpeed AnyRidge Internal Implant System	3.5 - 8.0	RP
MIS Internal Hex Dental Implant System (MIS® Seven®)	3.30	Narrow
	3.75	Standard
	4.20	Standard
	5.0	Wide
	6.0	Wide
Osstem Implant System	3.0	Mini

	3.5 4.0 - 7.0	Mini Regular
Straumann® Tissue Level	3.3/4.1/4.8 4.8	RN (4.8 mm) WN (6.5 mm)
Straumann® Bone Level	3.3 4.1/4.8	NC (3.3 mm) RC (4.1 mm)
Zimmer Tapered Screw-Vent®	3.7/4.1 4.7 6.0	3.5 mm 4.5 mm 5.7 mm

The zirconia superstructures for use with the Ti Base (Interface) are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) SUMMARY

I. SUBMITTER

IMPLANT PROTESIS DENTAL 2004, S.L
Carrer Rosa dels Vents, 9-15
08338 Premià de Dalt (Barcelona), Spain.

Contact Person:
Francesc Fumanal
+34 93 278 84 91
ffumanal@ipd2004.com

Date prepared: July 31, 2025.

II. DEVICE

Device name:	IPD DENTAL IMPLANT ABUTMENTS
Common Name:	ENDOSSEOUS DENTAL IMPLANT ABUTMENT
Classification Name:	Endosseous Dental Implant Abutment (21 CFR 872.3630)
Regulatory Class:	Class II
Product Code(s):	Primary: NHA; Secondary: PNP.

III. PREDICATE DEVICE(S):

Primary Predicate: K242819, IPD Dental Implant Abutments

Reference Devices: K240570, IPD Dental Implant Abutments,

The list of all the proposed third-party compatible dental implant systems, as additional Reference Devices, has been provided in **Table 1**.

Table 1. Reference Devices - Compatible Dental Implant Systems:

510(k) Holder	Compatible Implant/Abutment System	510(k) Number	510(k) Device Name
Astra Tech AB	OsseoSpeed™ Plus	K120414	OsseoSpeed™ Plus
Biohorizons Implant Systems, Inc.	BioHorizons Tapered Internal Implant System	K071638	BioHorizons Tapered Internal Implant System
Institut Straumann AG	Straumann® BLX Implant System	K173961	Straumann® BLX Implant System
Institut Straumann AG	Straumann BLX Ø3.5 mm Implants	K191256	Straumann BLX Ø3.5 mm Implants
Institut Straumann AG	Straumann® Bone Level	K140878	Straumann® Bone Level Tapered Implants
Institut Straumann AG	Straumann® Dental Implant System	K130222	Straumann® Tissue Level
Institut Straumann AG	Straumann® Screw-Retained Abutments	K192401	Straumann® Screw-Retained Abutments
MegaGen Implant Co., Ltd	Xpeed AnyRidge Internal Implant System	K140091	Xpeed AnyRidge Internal Implant System
MIS Implants Technologies Ltd.	MIS Internal Hex Dental Implant System (MIS® Seven®)	K180282	MIS Internal Hex Dental Implant System
OSSTEM Implant Co., Ltd.	Osstem Implant System	K161604	Osstem Implant System
Zimmer Biomet Dental	Tapered Screw-Vent®	K112160	Tapered Screw-Vent® X Implant

Note: *K140878 (Straumann® Bone Level) has been referenced just for informative purposes since Straumann® Screw-Retained Abutments (K192401) are mounted on the Straumann® Bone Level dental implant system.*

IV. DEVICE DESCRIPTION

IPD Dental Implant Abutments is a dental implant abutment system composed of dental abutments, screws, as well as other dental abutment accessories, intended to be placed into dental implants to provide support for dental prosthetic restorations.

Abutments provide basis for single or multiple tooth prosthetic restorations. They are available in a variety of connection types to enable compatibility with commercially available dental implants systems.

IPD Dental Implant Abutments includes the following categories of dental abutment designs:

- Titanium base (Interface) abutments (INC3D);
- Multi-Unit abutments (MUA);
- Overdenture Abutments (PSD);
- Temporary Abutments (PP);
- Healing Abutments (TC).

The system also includes the use of the corresponding screws intended to attach the prosthesis to the dental implant. Specifically:

- Ti Screw (TT): Used during restoration fabrication.
- TiN Screw (TTN): Used in finished restorations, with TiN coating.
- TPA Screw (TPA): Used in finished angulated restorations, with TiN coating.

The metallic components of the subject abutments and screws are made of titanium alloy conforming to ISO 5832-3 *"Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy"*.

The purpose of this submission is to expand IPD Dental Implant Abutments offerings with:

- New IPD's compatible dental implant systems,
- New angulations available abutment-category specific.
- New in-house TiN coating.

IPD dental implant abutments and screws are compatible with the following commercially available dental implant systems:

Table 2. Summary of IPD abutments categories with compatibilized OEM Implant/Abutment Systems with specific reference to maximum angulation specifically included in this submission.

Compatible Implant/Abutment System	Type of connection	Implant Diameter (mm)	Platform Diameter	Device category	Overdenture Abutment	Multi-Unit Abutment	Ti Base	Healing Abutment	Temporary Abutment
				Material	Titanium alloy, ISO 5832-3. TiN coated	Titanium alloy, ISO 5832-3. TiN coated	Titanium alloy, ISO 5832-3. TiN coated	Titanium alloy, ISO 5832-3. Uncoated	Titanium alloy, ISO 5832-3. Anodized
				IPD Abutment Systems					
Straumann® Tissue Level	Internal	3.3/4.1/4.8	RN (4.8 mm)	DA	RN (20º)	-	-	-	-
		4.8	WN (6.5 mm)		WN (20º)				
Straumann BLX Ø3.5 mm Implants	Internal	3.5	RB	DC	RB (20º)	-	-	-	-
Straumann® BLX Implant System		3.5 - 4.5	RB			-	-	-	-
		5.0 - 6.5	WB		WB (20º)				
Straumann® Screw-Retained Abutments	External	3.5	NC	DD	-	-	NC (30º)	NC	NC
		4.6	RC				RC (30º)	RC	RC
OsseoSpeed™ Plus	Internal	3.0	3.0	EB	-	3.0 (0º)	3.0 (0º)	3.0	3.0
		3.6	3.6			3.6 (30º)	-	-	-
		4.2	4.2			4.2 (30º)			
		4.8	4.8			4.8 (30º)	4.8 (28º)	4.8	4.8
Zimmer Tapered Screw-Vent®	Internal	3.7 / 4.1	3.5 mm	FA	-	3.5 (30º)	-	-	-
		4.7	4.5 mm			4.5 (30º)			
		6.0	5.7 mm			5.7 (30º)			
BioHorizons Tapered Internal Implant System	Internal	3.0	3.0	LB	-	3.0 (0º)	-	-	-
		3.4				-			
		3.8	3.5						
		4.6	4.5						
		5.8	5.7						
Osstem Implant System	Internal	3.0	Mini	OB	Mini (20º)	-	-	-	-
		3.5							
		4.0 - 7.0	Regular		Regular (20º)				
MIS Internal Hex Dental Implant System (MIS® Seven®)	Internal	3.30	Narrow	TA	-	Narrow (0º)	-	-	-
		3.75	Standard			Standard (30º)			
		4.20							
		5.0	Wide			Wide (30º)			
		6.0							
Xpeed AnyRidge Internal Implant System	Internal	3.5 - 8.0	RP	WB	-	RP (30º)	-	-	-

Please note that IPD Serie DD refers to Ti bases compatible with SRA system prosthetics mounted on Straumann Bone Level dental implants.

Ti Base (Interface) abutments are attached (screw-retained) to the implant/abutment and cemented to the zirconia superstructure.

The Ti Base is a two-piece abutment composed of the titanium component, as the bottom-half, and the zirconia superstructure, as the top-half. It consists of a pre-manufactured prosthetic component in Titanium alloy per ISO 5832-3, as well as the supporting digital library file for FDA-cleared design software (3Shape Abutment Designer™ Software, cleared under K151455) which enables the design of a patient-specific superstructure by the laboratory/clinician and which will be manufactured in FDA-cleared Zirconia (e.g., DD Bio Z, K142987) according to digital dentistry workflow at the point of care, or at a dental laboratory.

The design and fabrication of the zirconia superstructure for Ti Base (Interface) will be conducted using a digital dentistry workflow requiring the use of the following equipment, software and materials:

Scanner:	3D Scanner D850.
Design Software:	3Shape Abutment Designer Software, K151455.
Zirconia Material:	DD Bio Z, K142987.
Milling machine/Brand:	Dental Concept System Model: DC1 Milling System.
Cement:	Multilink® Automix, K123397.

Ti Base (Interface) abutment design parameters for the zirconia superstructure are defined as follows:

Minimum gingival height:	1.5 mm
Minimum wall thickness:	0.43 mm
Minimum post height for single-unit restorations:	4.75 mm (1)
Maximum gingival height:	6.0 mm
Maximum angulation of the final abutment	30° (2)

Note 1: Post height is the length above the abutment collar.
Note 2: In **Table 2** it has been specifically referred to the angulation depending on the dental implant system and platform.

The resulting final prosthetic restoration is screwed to the dental implant. All subject abutments are single-use and provided non-sterile. Final restoration (which includes the corresponding screw) is intended to be sterilized at the dental clinic before it is placed in the patient.

V. INDICATIONS FOR USE

IPD Dental Implant Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single or multiple dental prosthetic restorations.

Compatible Implant Systems

Compatible System	Implant/Abutment Diameter (mm)	Platform Diameter
OsseoSpeed™ Plus	3.0	3.0
	3.6	3.6
	4.2	4.2
	4.8	4.8
BioHorizons Tapered Internal Implant System	3.0	3.0
	3.4	3.0
	3.8	3.5
	4.6	4.5
	5.8	5.7
Straumann® BLX Implant System	3.5 - 4.5	RB
	5.0 - 6.5	WB
Straumann BLX Ø3.5 mm Implants	3.5	RB
Straumann® Screw-Retained Abutments	3.5	NC
	4.6	RC
Xpeed AnyRidge Internal Implant System	3.5 -8.0	RP
MIS Internal Hex Dental Implant System (MIS® Seven®)	3.30	Narrow
	3.75	Standard
	4.20	Standard
	5.0	Wide
	6.0	Wide
Osstem Implant System	3.0	Mini
	3.5	Mini
	4.0 - 7.0	Regular
Straumann® Tissue Level	3.3/4.1/4.8	RN (4.8 mm)
	4.8	WN (6.5 mm)
Straumann® Bone Level	3.3	NC (3.3 mm)
	4.1/4.8	RC (4.1 mm)
Zimmer Tapered Screw-Vent®	3.7 / 4.1	3.5 mm
	4.7	4.5 mm
	6.0	5.7 mm

Note: *K140878 (Straumann® Bone Level) has been referenced just for informative purposes since Straumann® Screw-Retained Abutments (K192401) are mounted on the Straumann® Bone Level dental implant system.*

The zirconia superstructures for use with the Ti Base (Interface) are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device is substantially equivalent in indications and design principles to the primary predicate device. Comparative tables of indications for use and relevant technological characteristics have been provided as follows.

Table 3. Indications for Use Statements.

<table>
<tr><th colspan="4">Indications for Use Statements</th></tr>
<tr><td colspan="4">Subject device</td></tr>
<tr><td>IPD Dental Implant Abutments (Implant Protesis Dental 2004, SL)</td><td colspan="3">IPD Dental Implant Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single or multiple dental prosthetic restorations.

Compatible Implant Systems

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<tr><th>Compatible System</th><th>Implant/Abutment Diameter (mm)</th><th>Platform Diameter</th></tr>
<tr><td rowspan="4">OsseoSpeed™ Plus</td><td>3.0</td><td>3.0</td></tr>
<tr><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 rowspan="5">BioHorizons Tapered Internal Implant System</td><td>3.0</td><td>3.0</td></tr>
<tr><td>3.4</td><td>3.0</td></tr>
<tr><td>3.8</td><td>3.5</td></tr>
<tr><td>4.6</td><td>4.5</td></tr>
<tr><td>5.8</td><td>5.7</td></tr>
<tr><td rowspan="2">Straumann® BLX Implant System</td><td>3.5 - 4.5</td><td>RB</td></tr>
<tr><td>5.0 - 6.5</td><td>WB</td></tr>
<tr><td>Straumann BLX Ø3.5 mm Implants</td><td>3.5</td><td>RB</td></tr>
<tr><td rowspan="2">Straumann® Screw-Retained Abutments</td><td>3.5</td><td>NC</td></tr>
<tr><td>4.6</td><td>RC</td></tr>
<tr><td>Xpeed AnyRidge Internal Implant System</td><td>3.5 -8.0</td><td>RP</td></tr>
<tr><td rowspan="5">MIS Internal Hex Dental Implant System (MIS® Seven®)</td><td>3.30</td><td>Narrow</td></tr>
<tr><td>3.75</td><td>Standard</td></tr>
<tr><td>4.20</td><td>Standard</td></tr>
<tr><td>5.0</td><td>Wide</td></tr>
<tr><td>6.0</td><td>Wide</td></tr>
<tr><td rowspan="3">Osstem Implant System</td><td>3.0</td><td>Mini</td></tr>
<tr><td>3.5</td><td>Mini</td></tr>
<tr><td>4.0 - 7.0</td><td>Regular</td></tr>
<tr><td rowspan="2">Straumann® Tissue Level</td><td>3.3/4.1/4.8</td><td>RN (4.8 mm)</td></tr>
<tr><td>4.8</td><td>WN (6.5 mm)</td></tr>
<tr><td rowspan="2">Straumann® Bone Level</td><td>3.3</td><td>NC (3.3 mm)</td></tr>
<tr><td>4.1/4.8</td><td>RC (4.1 mm)</td></tr>
<tr><td>Zimmer Tapered Screw-Vent®</td><td>3.7 / 4.1</td><td>3.5 mm</td></tr>
</table>
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</table>

		4.7	4.5 mm
		6.0	5.7 mm

The zirconia superstructures for use with the Ti Base (Interface) are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Predicate Devices

Primary Predicate Device

K242819
IPD Dental Implant Abutments (Implant Protesis Dental 2004, SL)

IPD Dental Implant Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single or multiple dental prosthetic restorations.

Compatible Implant Systems

Compatible Implant System	Implant Diameter (mm)	Platform Diameter
Astra Tech Implant System (Osseospeed®)	3.0	3.0
	3.5/4.0	3.5/4.0
	4.5/5.0	4.5/5.0
OsseoSpeed™ Plus	3.6	3.6
	4.2	4.2
BioHorizons Tapered Internal Implant System	3.0	3.0
	3.4	3.0
	3.8	3.5
	4.6	4.5
	5.8	5.7
3i Osseotite® Certain® Dental Implants	3.25	3.4
	4.0	4.1
	5.0	5.0
3i® Osseotite® Dental Implants	3.25	3.4
	4.0	4.1
	5.0	5.0
Straumann® BLX Implant System	3.5 - 4.5	RB
	5.0 - 6.5	WB
Straumann BLX Ø3.5 mm Implants	3.5	RB
Anyone™ Internal Implant System	3.5 -8.0	RP
Xpeed AnyRidge Internal Implant System	3.5 -8.0	RP
Conical Connection Implants (MIS® C1)	3.75	SP
	4.2	SP
MIS Internal Hex Dental Implant System (MIS® Seven®)	3.30	Narrow
	3.75	Standard
	4.20	Standard
	5.0	Wide
	6.0	Wide

	Osstem Implant System	3.0	Mini
		3.5	Mini
		4.0 - 7.0	Regular
	Neodent Implant System – GM Line	3.5 – 7.0	GM (Grand Morse)
	Nobel Biocare® Brånemark System	3.5	NP (3.5 mm)
		3.75/4.0	RP (4.1 mm)
		5.0	WP (5.1 mm)
	Nobel Biocare® Nobel Active®	3.0	3.0 mm
		3.5	NP (3.5 mm)
		4.3/5.0	RP (4.3 mm)
	Straumann® Tissue Level	3.3/4.1/4.8	RN (4.8 mm)
		4.8	WN (6.5 mm)
	Straumann® Bone Level	3.3	NC (3.3 mm)
		4.1/4.8	RC (4.1 mm)
	Zimmer Tapered Screw-Vent®	3.7 / 4.1	3.5 mm
		4.7	4.5 mm
		6.0	5.7 mm

The zirconia superstructures for use with the Ti Base (Interface) are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Reference Device

K240570
IPD Dental Implant Abutments (Implant Protesis Dental 2004, SL)

IPD Dental Implant Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single or multiple dental prosthetic restorations.

Compatible Implant Systems

Compatible Implant System	Implant Diameter (mm)	Platform Diameter
Astra Tech Implant System (Osseospeed®)	3.0	3.0
	3.5/4.0	3.5/4.0
	4.5/5.0	4.5/5.0
OsseoSpeed™ Plus	3.6	3.6
	4.2	4.2
BioHorizons Tapered Internal Implant System	3.0	3.0
	3.4	3.0
	3.8	3.5
	4.6	4.5
	5.8	5.7
3i Osseotite® Certain® Dental Implants	3.25	3.4
	4.0	4.1
	5.0	5.0
3i® Osseotite® Dental Implants	3.25	3.4
	4.0	4.1
	5.0	5.0

Straumann® BLX Implant System	3.5 - 4.5	RB
	5.0 - 6.5	WB
Straumann BLX Ø3.5 mm Implants	3.5	RB
Anyone™ Internal Implant System	3.5 -8.0	RP
Xpeed AnyRidge Internal Implant System	3.5 -8.0	RP
Conical Connection Implants (MIS® C1)	3.75	SP
	4.2	SP
MIS Internal Hex Dental Implant System (MIS® Seven®)	3.30	Narrow
	3.75	Standard
	4.20	Standard
	5.0	Wide
	6.0	Wide
Osstem Implant System	3.0	Mini
	3.5	Mini
	4.0 - 7.0	Regular

The zirconia superstructures for use with the Ti Base (Interface) are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Discussion on Indications for Use:

The indications for use of subject device in comparison with primary predicate device are verbatim, with the exception of the dental implant compatible systems which IPD is claiming compatibility in this submission, and which were most of them already included in previous premarket notification submissions. Further than this, no change in the intended use or indications for use of the IPD Dental Implant Abutments has been carried out. The devices are specifically indicated for patients undergoing oral implant surgery to provide support for dental prosthetic restorations.

Similarly, for the subject device and primary predicate device, the design and fabrication of the superstructure is conducted using the same digital dentistry workflow, requiring the use of the following equipment, software and materials:

Scanner:	3Shape scanner
Design Software:	3Shape Abutment Designer Software (K151455),
Zirconia Material:	DD Bio Z (K142987)
Milling machine:	Dental Concept System DC1 Milling System
Cement:	Multilink® Automix (K123397)

and using the supporting IPD digital library file for K151455.

The adequacy of the digital dentistry workflow for the subject device is substantiated by software validation and mechanical fatigue testing provided with the submission.

Reference device, K240570, has been selected due to abutment designs which were previously included in previous IPD submissions. Despite these, no further differences are found in the device categories and workflows included for subject and predicate devices.

It is IPD opinion that these differences do not affect the intended use of the subject device, and/or do not raise differences in terms of safety or efficacy.

Tables 4. Subject and Predicate devices technological characteristics comparison.

Characteristics	**Subject Device** IPD Dental Implant Abutments (IPD)	**Primary Predicate Device** IPD Dental Implant Abutments (IPD) K242819	**Reference Device** IPD Dental Implant Abutments (IPD) K240570
Materials			
Abutment Metallic Materials	Titanium Alloy Grade 5 (ISO 5832-3) + TiN or Anodized (TiO_2)	Titanium Alloy Grade 5 (ISO 5832-3) + TiN	Titanium Alloy Grade 5 (ISO 5832-3) + TiN or Anodized (TiO_2)
Screw Materials	Titanium Alloy Grade 5 (ISO 5832-3) + TiN	Titanium Alloy Grade 5 (ISO 5832-3) + TiN	Titanium Alloy Grade 5 (ISO 5832-3) + TiN
Superstructure	DD Bio Z Zirconia (K142987)	DD Bio Z Zirconia (K142987)	DD Bio Z Zirconia (K142987)
General Design Features			
Overview of abutment designs	Healing, Temporary, Ti-Base , Multi-Unit and Overdenture Abutments	Ti-Base , Multi-Unit and Overdenture Abutments	Healing, Temporary, Cementing and Ti-Base Abutments
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained
Restoration Type	Single-unit (crowns) Multiple-unit (bridges)	Single-unit (crowns) Multiple-unit (bridges)	Single-unit (crowns) Multiple-unit (bridges)
Abutment / Implant Platform Diameter (mm)	3.0 – 6.5	3.0 – 5.7	3.0 – 5.7
Abutment Angle	Maximum: 30°	Maximum: 30°	Maximum: 30°
General Abutment / Implant Connection	Internal and External	Internal and External	Internal and External
Sterilization			
Sterilization status and type	Non-sterile. End user steam sterilization	Non-sterile. End user steam sterilization	Non-sterile. End user steam sterilization

Specific Design features

Healing Abutments		
Characteristics	**IPD** Subject device	**IPD Dental Implant Abutments** **(K240570)**
Min – Max diameter	3.5 – 4.6	3.0 – 5.7
Angle	Straight (0°)	Straight (0°)
Intended restoration type	Single-unit	Single-unit
Method of fixation	Screw-retained	Screw-retained
Surface coating	Uncoated	Uncoated

Temporary Abutments		
Characteristics	**IPD** Subject device	**IPD Dental Implant Abutments** **(K240570)**
Min – Max diameter	3.5 – 4.6	3.0 – 5.7
Angle	Straight (0°)	Straight (0°)
Intended restoration type	Single-unit / Multi-unit	Single-unit / Multi-unit
Method of fixation	Cement-retained / Screw-retained	Cement-retained / Screw-retained
Surface coating	Anodized	Anodized

Multi-Unit Abutments		
Characteristics	**IPD** Subject device	**IPD Dental Implant Abutments** **(K242819)**
Abutment/Implant Platform diameter (mm)	3.0 – 4.8	3.0 – 7.0
Prosthetic Platform diameter (mm)	4.8	4.8
Gingival Height	1.0 – 4.5	0.9 – 5.0
Angle	0°, 17°, 30°	0°, 17°, 30°
Intended restoration type	Multi-unit	Multi-unit
Method of fixation	Screw-retained	Screw-retained
Surface coating	TiN coated	TiN coated

Overdenture Abutments		
Characteristics	**IPD** Subject device	**IPD Dental Implant Abutments** **(K242819)**
Abutment/Implant Platform diameter (mm)	3.5 – 6.5	3.3 – 7.0
Gingival Height	1.0 – 5.0	1.0 – 5.0
Divergence	± 20º	± 20º
Intended restoration type	Single-unit	Single-unit
Method of fixation	Screw-retained	Screw-retained
Surface coating	TiN coated	TiN coated

Ti Base Abutments		
Characteristics	**IPD** Subject device	**IPD Dental Implant Abutments** **(K242819)**
Min – Max diameter	3.0 – 4.8	3.0 – 5.7
Angle	Interface: Straight (0º)	Interface: Straight (0º)
Intended restoration type	Single-unit / Multi-unit	Single-unit / Multi-unit
Method of fixation	Cement-retained Screw-retained	Cement-retained Screw-retained
Surface coating	TiN	TiN

Superstructure Design w/ Ti Base (Interface)		
Characteristics	**IPD** Subject device	**IPD Dental Implant Abutments** **(K242819)**
Superstructure Design Workflow	The superstructures for use with the IPD Ti-Base abutments are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.	The superstructures for use with the IPD Ti-Base (Interface) abutments are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.
Zirconia CAD/CAM Design Parameters	Minimum Gingival height: 1.5 mm Minimum Wall Thickness: 0.43 mm Minimum Post Height: 4.75 mm (1) Maximum Gingival Height: 6 mm Maximum Angulation: 30º (2)	Minimum Gingival height: 1.5 mm Minimum Wall Thickness: 0.43 mm Minimum Post Height: 4.75 mm (1) Maximum Gingival Height: 6 mm Maximum Angulation: 30º

Note 1: Post height is the length above the abutment collar.
Note 2: Please consult Table 2 for specific angulation as per dental implant system and platform.

The data included in this submission demonstrate substantial equivalence to the predicate devices. It is considered that the subject device is substantially equivalent based on the following aspects:

- Has identical intended use;
- Uses identical operating principle;
- Incorporates similar design and identical device categories;
- Incorporates identical materials and surface coatings;
- It is sterilized using identical processes.

Ti Bases from subject device and primary predicate device are both intended to be used in a digital dentistry workflow which includes the scanning of patient's teeth setup, the design of the zirconia superstructure, the manufacturing of the superstructure, and the later cementation.

The adequacy of the digital dentistry workflow for the subject device is substantiated by software validation and mechanical fatigue testing provided in this submission, where applicable, based on IPD's role as abutment library provider, for combined and specific use with Ti Base (Interface).

Materials and technological characteristics of the subject device are identical to previously cleared in IPD Dental Implant Abutments (primary predicate device). Subject device categories are identical, with slight design differences adapted to compatible dental implant systems when compared to designs from device categories included in the predicates.

VII. PERFORMANCE DATA

The proposed devices have been subject to bench testing to determine fulfilment of design and performance requirements. Bench testing followed the recommendations provided in FDA Guidance Document – Class II Special Controls Guidance Document: *Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*.

Specifically, non-clinical performance testing on the IPD Dental Implant Abutments include:

- Sterilization validation to achieve a SAL of 1×10^{-6} according to ISO 17665-1 to ensure sterilization of the final finished device.
- Cytotoxicity testing according to ISO 10993-5 to demonstrate that all patient-contacting surfaces are non-cytotoxic. In addition to Sensitization (ISO 10993-10) and Irritation (ISO 10993-23) testing for TiN coated devices.
- Reverse engineering and dimensional analysis of original manufacturer's components (implants, abutments and screws) to confirm compatibility.
- Validation of the digital workflow and software system to ensure that design and manufacturing of the top half was within the specified design parameters.
- Static and dynamic fatigue testing of worst-case implant / abutment configurations and combinations in accordance with ISO 14801.
- Modified Surfaces Information per FDA's Class II Special Controls Guidance Document: *Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*.
- Non-clinical worst-case MRI review was performed to evaluate IPD Dental Implant Abutments in the MRI environment using scientific rationale and published literature (i.e., *Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795)*, for the entire system (including all variations of compatible implant bodies, dental abutments, and fixation screws) and material composition. 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.

Non-clinical performance testing leveraged from K242819 and K240570, together with that provided in current submission, showed that IPD Dental Implant Abutments met the applicable specifications and requirements.

No clinical testing was performed, the determination of substantial equivalence is supported by non-clinical testing.

VIII. CONCLUSIONS

The subject device and the primary predicate device have identical intended use, materials, and technological characteristics. The subject device and the primary and reference predicates devices encompass the same range of device categories, similar (OEM implant dependent) diameters, and similar designs. The subject device and primary predicate and reference devices are produced using identical materials and surface coatings, with identical fabrication processes, and are to be sterilized by the user using identical methods.

Based on the similarities observed and the results of non-clinical testing performed, it can be concluded that the data presented in the current submission demonstrate that the subject device, IPD Dental Implant Abutments, is substantially equivalent to the predicate devices.