Implant Protesis Dental 2004, S.l.
Francesc Fumanal
Regulatory Affairs Manager
Carrer Rosa dels Vents, 9-15.
Premià de Dalt (Barcelona), 08338
SPAIN

January 22, 2026

Re: K253253
Trade/Device Name: IPDmilled Blanks
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: December 15, 2025
Received: December 16, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K253253

Device Name

IPDmilled Blanks

Indications for Use *(Describe)*

IPDmilled Blanks are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed CAD/CAM customizations for the IPDmilled Blanks are to be designed and manufactured according to digital dentistry workflow or to be sent to an IPD validated milling center for manufacture. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

Compatible Implant Systems

Compatible Implant System	Implant Diameter (mm)	Platform Diameter
Dentium Co., Ltd Implantium	3.6	RP
	4.0	
	4.5	
	5.0	
	6.0	
	7.0	
Friadent Implant Systems	3.8	D 3.8
	4.5	D 4.5
Neoss ProActive Implant	3.25	NP
	3.5	SP
	4.0	
	4.5	
	5.0	
	5.5	
SPI® Dental Implant, Inicell®	3.5	PF Ø 3.5
	4.0	PF Ø 4.0
	4.2	PF Ø 4.5
	5.0	PF Ø 5.0
	6.0	PF Ø 6.0
BEGO Semados® S-Line	3.25	Ø 3.25
	3.75	Ø 3.75
	4.1	Ø 4.1
	4.5	Ø 4.5
	5.5	Ø 5.5
ANKYLOS® C/X Implant System	3.5	C/X
	4.5	
	5.5	
	7.0	
MIS V3 Conical Connection Dental Implant System	3.75	SP
	4.2	
Conical Connection Implants	3.75	SP

Compatible Implant System	Implant Diameter (mm)	Platform Diameter
(MIS® C1)	4.2	
MIS C1 Narrow Platform Conical Connection Implant System	3.3	NP
MIS C1 Wide Platform Conical Connection Abutments	5.0	WP
PRAMA White Implant Systems	3.8	Collex
	4.25	
	5.0	
Altatec GmbH CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants	3.3	Ø 3.3
	3.8	Ø 3.8
	4.3	Ø 4.3
	5.0	Ø 5.0
Straumann TLX Implant System	3.75	NT
	4.5	
	3.75	RT
	4.5	
	5.5	WT
	6.5	
Kontact Dental Implant System	RP	RP
ICX-Implant System	RP	RP
Tapered Pro Conical Implant System	3.3	Narrow
	3.8	
	4.2	Regular
	4.6	
	5.2	
Straumann® Tissue Level	3.3	RN Ø 4.8
	4.1	
	4.8	
	4.8	WN Ø 6.5
Zimmer Tapered Screw-Vent®	3.7	Ø 3.5
	4.1	
	4.7	Ø 4.5
	6.0	Ø 5.7
Nobel Biocare® Nobel Active®	3.5	NP Ø 3.5
	4.3	RP Ø 4.3
	5.0	
Straumann® Bone Level Tapered Implants	3.3	NC Ø 3.3
	4.1	RC Ø 4.1
	4.8	
Neodent Implant System – GM Line	3.5	GM (Grand Morse)
	3.75	
	4.0	
	4.3	
	5.0	
	6.0	
	7.0	
Osstem Implant System	3.0	M Ø 3.5
	3.5	
	4.0 - 7.0	R Ø 4.0
Xpeed AnyRidge Internal Implant System	3.5 -8.0	RP
3i Osseotite® Certain® Dental Implants	3.25	NP Ø 3.4
	4.0	RP Ø 4.1
	5.0	WP Ø 5.0
Astra Tech Implant System (Osseospeed®)	3.5/4.0	Aqua Ø3.5-Ø4.0
	4.5/5.0	Lilac Ø4.5- Ø5.0
OsseoSpeed™ Plus	3.0	XS Ø3.0
	3.6	S Ø3.6
	4.2	M Ø4.2
	4.8	L Ø4.8
	5.4	XL Ø5.4
BioHorizons Tapered Internal Implant System	3.0	Ø 3.0
	3.4	
	3.8	Ø 3.5

Compatible Implant System	Implant Diameter (mm)	Platform Diameter
	4.6	Ø 4.5
	5.8	Ø 5.7
MIS Internal Hex Dental Implant System (MIS® Seven®)	3.30	Narrow NP Ø3.30
	3.75	Standard SP
	4.20	
	5.0	Wide WP
	6.0	
Straumann BLX Ø3.5 mm Implants	3.5	RB
Straumann® BLX Implant System	3.5 – 4.5	RB
	5.0 – 6.5	WB
ALTATEC Camlog Screwline Implant System	3.3	Ø 3.3
	3.8	Ø 3.8
	4.3	Ø 4.3
	5.0	Ø 5.0
Replace TiUnite Endosseous Implant	3.5	NP Ø3.5
	4.3	RP Ø4.3
	5.0	WP Ø5.0

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: January 16, 2025.

II. DEVICE

Device name:	IPDmilled Blanks
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:	K240982, DESS Dental Smart Solutions
Reference Devices:	K151455, 3Shape Abutment Designer™ Software, K193352, AbutmentCAD,

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 System	510(k) Number	510(k) Device Name
Dentium Co., Ltd	Dentium Co., Ltd Implantium	K041368	Dentium Co., Ltd Implantium
Dentsply International, Incorporated	Friadent Implant Systems	K073075	Friadent Implant Systems
Neoss Ltd	Neoss ProActive Implant	K083561	Neoss ProActive Implant
Thomen Medical AG	SPI® Dental Implant, Inicell®	K090154	SPI® Dental Implant, Inicell®
BEGO Implant Systems GmbH & Co KG	BEGO Semados® S-Line	K090716	BEGO Semados® S-Line
MIS Implants Technologies Ltd.	Conical Connection Dental Implants	K112162	Conical Connection Dental Implants
Denstply International, Inc.	ANKYLOS® C/X Implant System	K140347	ANKYLOS® C/X Implant System
MIS Implants Technologies Ltd.	MIS V3 Conical Connection Dental Implant System	K163349	MIS V3 Conical Connection Dental Implant System
MIS Implants Technologies Ltd.	MIS C1 Narrow Platform Conical Connection Implant System MIS C1 Wide Platform Conical Connection Abutments	K172505	MIS C1 Narrow Platform Conical Connection Implant System MIS C1 Wide Platform Conical Connection Abutments
Sweden & Martina S.p.A.	PRAMA White Implant Systems	K180365	PRAMA White Implant Systems
Altatec GmbH	Altatec GmbH CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants	K193401	Altatec GmbH CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants
Institut Straumann AG	Straumann TLX Implant System	K200586	Straumann TLX Implant System
Biotech Dental, SAS	Kontact Dental Implant System	K213997	Kontact Dental Implant System
medentis medical GmbH	ICX-Implant System	K231566	ICX-Implant System
BioHorizons Implant Systems Inc.	Tapered Pro Conical Implant System	K240187	Tapered Pro Conical Implant System
Institut Straumann AG	Straumann® Bone Level Tapered Implants	K140878	Straumann® Bone Level Tapered Implants l
Astra Tech AB	OsseoSpeed™ Plus	K120414	OsseoSpeed™ Plus
Institut Straumann AG	Straumann® Tissue Level	K130222	Straumann® Tissue Level
BioHorizons Implant Systems, Inc.	BioHorizons Tapered Internal Implant System	K071638	BioHorizons Tapered Internal Implant System
Astra Tech AB	Astra Tech Implant System (Osseospeed®)	K101732	Astra Tech Implant System (Osseospeed®)
Zimmer Dental Inc.	Zimmer Tapered Screw-Vent®	K112160	Tapered Screw-Vent® X Implant
MIS Implants Technologies Ltd.	MIS Internal Hex Dental Implant System (MIS® Seven®)	K180282	MIS Internal Hex Dental Implant System

510(k) Holder	Compatible Implant System	510(k) Number	510(k) Device Name
Nobel Biocare AB	Nobel Biocare® Nobel Active®	K142260	Nobel Active®
OSSTEM Implant Co., Ltd.	Osstem Implant System	K161604	Osstem Implant System
MegaGen Implant Co., Ltd	Xpeed AnyRidge Internal Implant System	K140091	Xpeed AnyRidge Internal Implant System
Implant Innovations, Inc.	3i Osseotite® Certain® Dental Implants	K063341	3i Osseotite® Certain® Dental Implants
Altatec Biotechnologies N .A., Incorporated	ALTATEC Camlog Screwline Implant System	K022425	ALTATEC Camlog Screwline Implant System
Nobel Biocare USA, Inc.	Replace TiUnite Endosseous Implant	K023113	Replace TiUnite Endosseous Implant
JJGC Indústria e Comércio de Materiais Dentários SA	Neodent Implant System – GM Line	K163194	Neodent Implant System – GM Line
Institut Straumann AG	Straumann BLX Ø 3.5 Implant System	K191256	Straumann BLX Ø 3.5 Implant System
Institut Straumann AG	Straumann® BLX Implant System	K173961	Straumann® BLX Implant System

IV. DEVICE DESCRIPTION

The purpose of this submission is to expand abutment categories of IPD Dental Implant Abutments, which were previously cleared.

IPDmilled Blanks is a dental implant abutment system composed of dental abutments and screws 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. IPDmilled Blanks have a pre-manufactured connection interface that fits directly with a pre-specified dental implant. The customized shape of the abutment is intended to be designed and manufactured according to a digital dentistry workflow or to be sent to an IPD validated milling center for manufacture. IPDmilled Blank is delivered non-sterile and the final restoration, including the screw, is intended to be sterilized at the dental clinic before it is placed in the patient.

The IPDmilled Blanks are blistered together with their specific screw. The screws are intended to attach the prosthesis to the dental implant.

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 design and manufacturing of the custom abutment will be conducted using a digital dentistry workflow requiring the use of the following equipment and software:

Intraoral Scanner:	3Shape TRIOS A/S Series
Desktop Scanner:	3Shape E Series.
Design Software:	3Shape Abutment Designer Software, K151455. AbutmentCAD, K193352.
Milling unit:	CORiTEC 350i PRO / CORiTEC 350i Loader PRO with MillBox CAM software.

IPDmilled Blank libraries' have built-in design limitations, and the user isn't allowed to exceed these limitations. The custom abutment design limitation specifications are as follows:

Minimum gingival height:	0.5 mm
Maximum gingival height:	6.0 mm
Minimum wall thickness:	0.4 mm
Minimum post height:	4.0 mm (1)

All IPDmilled Blanks are for straight abutments only.
Note 1: Post height is the length above the abutment collar.

IPDmilled Blanks are compatible with the following commercially available dental implant systems:

Table 2. Summary of IPDmilled Blanks compatibilized with OEM Implant Systems specifically included in this submission.

Compatible Dental Implant System	Type of connection	Implant Diameter (mm)	Platform Diameter	Device category Material IPD Series	IPDmilled Blanks Titanium alloy, ISO 5832-3. Uncoated
Dentium Co., Ltd Implantium	Internal	3.6	RP	XA	☑
		4.0			
		4.5			
		5.0			
		6.0			
		7.0			
Friadent Implant Systems	Internal	3.8	D 3.8	IA	☑
		4.5	D 4.5		
Neoss ProActive Implant	Internal	3.25	NP	6A	☑
		3.5	SP		
		4.0			
		4.5			
		5.0			
		5.5			
SPI® Dental Implant, Inicell®	Internal	3.5	PF Ø 3.5	7A	☑
		4.0	PF Ø 4.0		
		4.2	PF Ø 4.5		
		5.0	PF Ø 5.0		
		6.0	PF Ø 6.0		
BEGO Semados® S-Line	Internal	3.25	Ø 3.25	SB	☑
		3.75	Ø 3.75		
		4.1	Ø 4.1		
		4.5	Ø 4.5		
		5.5	Ø 5.5		
ANKYLOS® C/X Implant System	Internal	3.5	C/X	IB	☑
		4.5			
		5.5			
		7.0			
MIS V3 Conical Connection Dental Implant System	Internal	3.75	SP	TB	☑
		4.2			
Conical Connection Implants	Internal	3.75	SP		

Compatible Dental Implant System	Type of connection	Implant Diameter (mm)	Platform Diameter	Device category Material IPD Series	IPDmilled Blanks Titanium alloy, ISO 5832-3. Uncoated
(MIS® C1)		4.2			☑
MIS C1 Narrow Platform Conical Connection Implant System	Internal	3.3	NP		☑
MIS C1 Wide Platform Conical Connection Abutments	Internal	5.0	WP		☑
PRAMA White Implant Systems	Internal	3.8	Collex	MB	☑
		4.25			
		5.0			
Altatec GmbH CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants	Internal	3.3	Ø 3.3	JB	☑
		3.8	Ø 3.8		
		4.3	Ø 4.3		
		5.0	Ø 5.0		
Straumann TLX Implant System	Internal	3.75	NT	DE	☑
		4.5			
		3.75	RT		
		4.5			
		5.5	WT		
		6.5			
Kontact Dental Implant System	Internal	RP	RP	QB	☑
ICX-Implant System	Internal	RP	RP	YB	☑
Tapered Pro Conical Implant System	Internal	3.3	Narrow	JB	☑
		3.8			
		4.2	Regular		
		4.6			
		5.2			
Straumann® Tissue Level	Internal	3.3	RN Ø 4.8	DA	☑
		4.1			
		4.8			
		4.8	WN Ø 6.5		
Zimmer Tapered Screw-Vent®	Internal	3.7	Ø 3.5	FA	☑
		4.1			
		4.7	Ø 4.5		
		6.0	Ø 5.7		
Nobel Biocare® Nobel Active®	Internal	3.5	NP Ø 3.5	AD	

Compatible Dental Implant System	Type of connection	Implant Diameter (mm)	Platform Diameter	Device category Material IPD Series	IPDmilled Blanks Titanium alloy, ISO 5832-3. Uncoated
		4.3	RP Ø 4.3		☑
		5.0			
Straumann® Bone Level Tapered Implants	Internal	3.3	NC Ø 3.3	DB	☑
		4.1	RC Ø 4.1		
		4.8			
Neodent Implant System – GM Line	Internal	3.5	GM (Grand Morse)	RB	☑
		3.75			
		4.0			
		4.3			
		5.0			
		6.0			
		7.0			
Osstem Implant System	Internal	3.0	M Ø 3.5	OB	☑
		3.5			
		4.0 - 7.0	R Ø 4.0		
Xpeed AnyRidge Internal Implant System	Internal	3.5 -8.0	RP	WB	☑
3i Osseotite® Certain® Dental Implants	Internal	3.25	NP Ø 3.4	BB	☑
		4.0	RP Ø 4.1		
		5.0	WP Ø 5.0		
Astra Tech Implant System (Osseospeed®)	Internal	3.5/4.0	Aqua Ø3.5-Ø4.0	EA	☑
		4.5/5.0	Lilac Ø4.5- Ø5.0		
OsseoSpeed™ Plus	Internal	3.0	XS Ø3.0	EB	☑
		3.6	S Ø3.6		
		4.2	M Ø4.2		
		4.8	L Ø4.8		
		5.4	XL Ø5.4		
BioHorizons Tapered Internal Implant System	Internal	3.0	Ø 3.0	LB	☑
		3.4			
		3.8	Ø 3.5		
		4.6	Ø 4.5		
		5.8	Ø 5.7		
MIS Internal Hex Dental Implant System (MIS® Seven®)	Internal	3.30	Narrow NP Ø3.30	TA	☑
		3.75	Standard SP		

Compatible Dental Implant System	Type of connection	Implant Diameter (mm)	Platform Diameter	Device category Material IPD Series	IPDmilled Blanks Titanium alloy, ISO 5832-3. Uncoated
		4.20			
		5.0	Wide WP		
		6.0			
Straumann BLX Ø3.5 mm Implants	Internal	3.5	RB	DC	☑
Straumann® BLX Implant System		3.5 – 4.5	RB		
		5.0 – 6.5	WB		
ALTATEC Camlog Screwline Implant System	Internal	3.3	Ø 3.3	JA	☑
		3.8	Ø 3.8		
		4.3	Ø 4.3		
		5.0	Ø 5.0		
Replace TiUnite Endosseous Implant	Internal	3.5	NP Ø3.5	AC	☑
		4.3	RP Ø4.3		
		5.0	WP Ø5.0		

V. INDICATIONS FOR USE

IPDmilled Blanks are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed CAD/CAM customizations for the IPDmilled Blanks are to be designed and manufactured according to digital dentistry workflow or to be sent to an IPD validated milling center for manufacture. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

Compatible Implant Systems

Compatible Dental Implant System	Implant Diameter (mm)	Platform Diameter
Dentium Co., Ltd Implantium	3.6	RP
	4.0	
	4.5	
	5.0	
	6.0	
	7.0	
Friadent Implant Systems	3.8	D 3.8
	4.5	D 4.5
Neoss ProActive Implant	3.25	NP
	3.5	SP
	4.0	
	4.5	
	5.0	
	5.5	
SPI® Dental Implant, Inicell®	3.5	PF Ø 3.5
	4.0	PF Ø 4.0
	4.2	PF Ø 4.5
	5.0	PF Ø 5.0
	6.0	PF Ø 6.0
BEGO Semados® S-Line	3.25	Ø 3.25
	3.75	Ø 3.75
	4.1	Ø 4.1
	4.5	Ø 4.5
	5.5	Ø 5.5
ANKYLOS® C/X Implant System	3.5	C/X
	4.5	
	5.5	
	7.0	
MIS V3 Conical Connection Dental Implant System	3.75	SP
	4.2	
Conical Connection Implants (MIS® C1)	3.75	SP
	4.2	
MIS C1 Narrow Platform Conical Connection Implant System	3.3	NP
MIS C1 Wide Platform Conical Connection Abutments	5.0	WP
PRAMA White Implant Systems	3.8	Collex
	4.25	

Compatible Dental Implant System	Implant Diameter (mm)	Platform Diameter
	5.0	
Altatec GmbH CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants	3.3	Ø 3.3
	3.8	Ø 3.8
	4.3	Ø 4.3
	5.0	Ø 5.0
Straumann TLX Implant System	3.75	NT
	4.5	
	3.75	RT
	4.5	
	5.5	WT
	6.5	
Kontact Dental Implant System	RP	RP
ICX-Implant System	RP	RP
Tapered Pro Conical Implant System	3.3	Narrow
	3.8	
	4.2	Regular
	4.6	
	5.2	
Straumann® Tissue Level	3.3	RN Ø 4.8
	4.1	
	4.8	
	4.8	WN Ø 6.5
Zimmer Tapered Screw-Vent®	3.7	Ø 3.5
	4.1	
	4.7	Ø 4.5
	6.0	Ø 5.7
Nobel Biocare® Nobel Active®	3.5	NP Ø 3.5
	4.3	RP Ø 4.3
	5.0	
Straumann® Bone Level Tapered Implants	3.3	NC Ø 3.3
	4.1	RC Ø 4.1
	4.8	
Neodent Implant System – GM Line	3.5	GM (Grand Morse)
	3.75	
	4.0	
	4.3	
	5.0	
	6.0	
	7.0	
Osstem Implant System	3.0	M Ø 3.5
	3.5	
	4.0 - 7.0	R Ø 4.0
Xpeed AnyRidge Internal Implant System	3.5 -8.0	RP
3i Osseotite® Certain® Dental Implants	3.25	NP Ø 3.4
	4.0	RP Ø 4.1
	5.0	WP Ø 5.0
Astra Tech Implant System (Osseospeed®)	3.5/4.0	Aqua Ø3.5-Ø4.0
	4.5/5.0	Lilac Ø4.5- Ø5.0
OsseoSpeed™ Plus	3.0	XS Ø3.0

Compatible Dental Implant System	Implant Diameter (mm)	Platform Diameter
	3.6	S Ø3.6
	4.2	M Ø4.2
	4.8	L Ø4.8
	5.4	XL Ø5.4
BioHorizons Tapered Internal Implant System	3.0	Ø 3.0
	3.4	
	3.8	Ø 3.5
	4.6	Ø 4.5
	5.8	Ø 5.7
MIS Internal Hex Dental Implant System (MIS® Seven®)	3.30	Narrow NP Ø3.30
	3.75	Standard SP
	4.20	
	5.0	Wide WP
	6.0	
Straumann BLX Ø3.5 mm Implants	3.5	RB
Straumann® BLX Implant System	3.5 – 4.5	RB
	5.0 – 6.5	WB
ALTATEC Camlog Screwline Implant System	3.3	Ø 3.3
	3.8	Ø 3.8
	4.3	Ø 4.3
	5.0	Ø 5.0
Replace TiUnite Endosseous Implant	3.5	NP Ø3.5
	4.3	RP Ø4.3
	5.0	WP Ø5.0

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.

Indications for Use Statements	
Subject device	
IPDmilled Blanks (Implant Protesis Dental 2004, SL)	IPDmilled Blanks are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed CAD/CAM customizations for the IPDmilled Blanks are to be designed and manufactured according to digital dentistry workflow or to be sent to an IPD validated milling center for manufacture. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, milling machine and associated tooling and accessories. *For complete Indications for Use Statement on OEM Compatibility see Form FDA 3881.*
Predicate Devices	
Primary Predicate Device	
K240982 DESS Dental Smart Solutions (Terrats Medical, SL)	DESS Dental Smart Solutions abutments are intended to be used in conjunction with 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. All digitally designed custom abutments for use with DESS Bases or Pre-milled Blanks are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories. *For complete Indications for Use Statement on OEM Compatibility see Form FDA 3881.*

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.

The devices are specifically indicated for patients undergoing oral implant surgery to provide support for dental prosthetic restorations.

Similarly, both the subject device and primary predicate device (K240982) custom abutments, are to be designed and manufactured using a digital dentistry workflow or to be sent to a validated milling center for manufacture. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, milling machine, and associated tooling and accessories.

It is IPD opinion that any potential difference does 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.

Comparison Item	Subject Device	Predicate Device
	IPDmilled Blanks (IMPLANT PROTESIS DENTAL 2004, S.L.)	DESS Dental Smart Solutions (K240982) (Terrats Medical SL)
Product Code	NHA, PNP	NHA, PNP
Reason for predicate selection	Predicate has been selected due to the similarities of the abutment category design and digital workflow.	
Intended use	Support of a prosthesis to restore chewing function.	Support of a prosthesis to restore chewing function
Design		
Abutment Design	Customized abutment mounted on the implant and fixed with a screw.	Customized abutment mounted on the implant and fixed with a screw.
Prosthesis Attachment	Screw-cement retained	Screw-cement retained
Restoration	Single-unit / Multi-unit	Single-unit / Multi-unit
Abutment/Implant Platform Diameter (mm)	3.0-7.0	2.52 – 6.5
Abutment Angle	0° (Straight)	Max. 30°
Material		
Abutment Material (Blanks)	Titanium Alloy Grade 5 (ISO 5832-3)	Ti-6AI-4V ELI
Screw Material	Titanium Alloy Grade 5 (ISO 5832-3)	Ti-6AI-4V ELI
Surface & Coating	Uncoated	Uncoated
Design & Manufacturing Workflow		
Type	Digital Dentistry Workflow	Digital Dentistry Workflow & Validated Milling Center
Design Workflow	Intraoral Scanner: 3Shape TRIOS A/S Series Desktop Scanner: 3Shape E Series. Design Software: 3Shape Abutment Designer Software, K151455; AbutmentCAD, K193352.	Intraoral Scanner: 3Shape TRIOS e-series Desktop Scanner: D/R2000 Lab Scanner. Design Software: 3Shape Abutment Designer Software, K151455; AbutmentCAD, K193352.
Manufacturing Workflow	CORiTEC 350i PRO / CORiTEC 350i Loader PRO with MillBox CAM software.	VHF R5 By vhf camfacture AG with DentalCAM & DentalCNC
Custom Abutment Design parameters	Minimum gingival height: 0.5 mm Maximum gingival height: 6.0 mm Minimum wall thickness: 0.4 mm Minimum post height: 4.0 mm	Minimum gingival height: 0.5 mm Maximum gingival height: 6.0 mm Minimum wall thickness: 0.4 mm Minimum post height: 4.0 mm
Sterilization		
Sterilization status and Method	Non-sterile. End user steam sterilization	Non-sterile. End user steam sterilization

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 the same intended use;
- Uses the same operating principle;
- Incorporates similar design and same device categories;
- Incorporates same materials;
- It is sterilized using the same processes.

VII. PERFORMANCE DATA

Non-clinical performance testing submitted (either in subject or predicate submission) include:

- Sterilization validation to achieve a SAL of 1 x 10^{-6} according to ISO 17665-1 to ensure sterilization of the final finished device, leveraged from previous submissions.
- Cytotoxicity testing according to ISO 10993-5 to demonstrate that all patient-contacting surfaces are non-cytotoxic.
- Reverse engineering and dimensional analysis of original manufacturer's components (implants, abutments and screws) to confirm compatibility.
- Validation of the digital workflow, including Scanners, CAD and CAM Software and Milling unit. The validation provided for the abutment design library does not allow the user to design outside the design limitation specifications set. The CAD-CAM software prevents designing outside the specified design limits in the library file. To address the potential risk of damage to the implant-abutment connection geometry during the milling of the patient-matched portions of the custom abutment, verification testing of the CAM restriction zones was conducted, including verification to show avoidance of damage or modifications of the connection geometry, and locking of restriction zones from user editing in the CAM software.
- Non-clinical worst-case MRI review was performed to evaluate the devices 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 previous submission, together with that provided in current submission, showed that IPDmilled Blanks 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 the same intended use and materials, and similar technological characteristics. The subject device and the primary predicate device encompass the same device category, and similar (OEM implant dependent) diameters and designs. The subject and primary predicate device 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, IPDmilled Blanks, is substantially equivalent to the predicate devices.