



October 10, 2023

Implant Protesis Dental 2004, S.L.
Francesc Fumanal
Regulatory Affairs Manager
Cami del Mig. 71. 1º 2º
Mataro, Barcelona 08302
SPAIN

Re: K231413

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: September 6, 2023
Received: September 6, 2023

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.

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

510(k) Number (if known)

K231413

Device Name

IPD DENTAL IMPLANT ABUTMENTS

Indications for Use (Describe)

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

Implant System Compatibility	Implant Diameter (mm)	Platform Diameter
NobelActive®	3.0	3.0 mm
	3.5	NP (3.5 mm)
	4.3/5.0	RP (4.3 mm)
Straumann® Bone Level	3.3	NC (3.3 mm)
	4.1/4.8	RC (4.1 mm)
Neodent Implant System – GM Line	3.5 – 7.0	GM (Grand Morse)
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.

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
PRStaff@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 93 672 110 748
ffumanal@ipd2004.com

Date prepared: October 10th, 2023.

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: K222215, IPD Dental Implant Abutments
Reference Device: K222288, DESS Dental Smart Solutions

Compatible Implant Systems		
Clearance	Device	Manufacturer
K142260	Nobel Active®	Nobel Biocare AB
K140878	Straumann® Bone Level	Institut Straumann AG
K163194	Neodent Implant System – GM Line	JJGC Indústria e Comércio de Materiais Dentários SA
K112160	Tapered Screw-Vent®	Zimmer Biomet Dental

IV. DEVICE DESCRIPTION

IPD Dental Implant Abutments 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.

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

- Healing abutments;
- Temporary abutments;
- Cementing titanium abutments;
- Titanium base (interface) abutments;

The system also includes the corresponding Titanium Screws intended to attach the prosthesis to the dental implant. Specifically:

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

All 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 cleared under K222215 to:

- Include new OEM dental implant platform compatibilities (previously not cleared) for previously cleared IPD’s abutment designs,
- include previously-cleared OEM platform compatibilities for previously-cleared IPD’s abutment designs for which the specific combinations of compatibility and design were not cleared previously, and,
- Add angulation to previously Ti Base (Interface) abutments (design parameters for the zirconia superstructure).

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

Table 5.1. Summary of IPD abutments categories with compatibilized OEM Implant Systems.

Compatible Implant System	Type of connection	Implant Diameter (mm)	Platform Diameter	Device category	Healing Abutment	Cementing / Temporary Abutments	Ti Base (Interface) Abutment
				Material	Titanium alloy, ISO 5832-3	Titanium alloy, ISO 5832-3, Temp. Anodized	Titanium alloy, ISO 5832-3, TiN coated
				IPD Abutment Systems			
Nobel Active®	Internal	3.0 3.5 4.3/5.0	3.0 mm NP (3.5 mm) RP (4.3 mm)	AD	3.0 3.5 4.3	3.0 3.5 4.3	3.0 3.5 4.3
Straumann® Bone Level	Internal	3.3 4.1/4.8	NC (3.3 mm) RC (4.1 mm)	DB	3.3 4.1	3.3 4.1	3.3 4.1
Neodent Implant System – GM Line	Internal	3.5 – 7.0	GM (Grand Morse)	RB	GM	GM	GM
Tapered Screw-Vent®	Internal	3.7 / 4.1 4.7 6.0	3.5 mm 4.5 mm 5.7 mm	FA	* * 5.7	*	*

(*) Previously cleared under K222215.

The abovementioned Compatible Implant Systems received FDA-clearance with the following 510(k) concurrence numbers: Nobel Active® K142260; Straumann® Bone Level Tapered Implants K140878, Neodent Implant System – GM Line K163194, and Tapered Screw-Vent K113756 (*aka* Tapered Screw-Vent® X Implant).

Ti Base (Interface) abutments are used as an interface between the dental implant and the zirconia superstructure. They are attached (screw-retained) to the implant and cemented to the zirconia superstructure.

The Ti Base (Interface) is a two-piece abutment composed of the Ti Base (Interface) 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 (e.g., 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 Bases (Interfaces) will be conducted using a digital dentistry workflow requiring the use of the following equipment:

- 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) abutments design parameters for the zirconia superstructure are defined as follows:

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

The laboratory designed superstructure is attached to Ti Base (Interface) by the use of an FDA-cleared cement (e.g., Multilink® Automix, K123397). 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

Implant System Compatibility	Implant Diameter (mm)	Platform Diameter
NobelActive®	3.0 3.5 4.3/5.0	3.0 mm NP (3.5 mm) RP (4.3 mm)
Straumann® Bone Level	3.3 4.1/4.8	NC (3.3 mm) RC (4.1 mm)
Neodent Implant System – GM Line	3.5 – 7.0	GM (Grand Morse)
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.

¹ With the exception of Nobel Active® 3.0 and 3.5 mm-platforms which final abutment is straight (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 in the following pages.

Table 5.2. Indications for Use Statements.

Indications for Use Statements																											
Subject device																											
IPD Dental Implant Abutments (Implant Prothesis Dental 2004, SL)	<p>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.</p> <p style="text-align: center;"><u>Compatible Implant Systems</u></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #D3D3D3;">Implant System Compatibility</th> <th style="background-color: #D3D3D3;">Implant Diameter (mm)</th> <th style="background-color: #D3D3D3;">Platform Diameter</th> </tr> </thead> <tbody> <tr> <td rowspan="3" style="text-align: center;">NobelActive®</td> <td style="text-align: center;">3.0</td> <td style="text-align: center;">3.0 mm</td> </tr> <tr> <td style="text-align: center;">3.5</td> <td style="text-align: center;">NP (3.5 mm)</td> </tr> <tr> <td style="text-align: center;">4.3/5.0</td> <td style="text-align: center;">RP (4.3 mm)</td> </tr> <tr> <td rowspan="2" style="text-align: center;">Straumann® Bone Level</td> <td style="text-align: center;">3.3</td> <td style="text-align: center;">NC (3.3 mm)</td> </tr> <tr> <td style="text-align: center;">4.1/4.8</td> <td style="text-align: center;">RC (4.1 mm)</td> </tr> <tr> <td style="text-align: center;">Neodent Implant System – GM Line</td> <td style="text-align: center;">3.5 – 7.0</td> <td style="text-align: center;">GM (Grand Morse)</td> </tr> <tr> <td rowspan="3" style="text-align: center;">Tapered Screw-Vent®</td> <td style="text-align: center;">3.7 / 4.1</td> <td style="text-align: center;">3.5 mm</td> </tr> <tr> <td style="text-align: center;">4.7</td> <td style="text-align: center;">4.5 mm</td> </tr> <tr> <td style="text-align: center;">6.0</td> <td style="text-align: center;">5.7 mm</td> </tr> </tbody> </table> <p>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.</p>		Implant System Compatibility	Implant Diameter (mm)	Platform Diameter	NobelActive®	3.0	3.0 mm	3.5	NP (3.5 mm)	4.3/5.0	RP (4.3 mm)	Straumann® Bone Level	3.3	NC (3.3 mm)	4.1/4.8	RC (4.1 mm)	Neodent Implant System – GM Line	3.5 – 7.0	GM (Grand Morse)	Tapered Screw-Vent®	3.7 / 4.1	3.5 mm	4.7	4.5 mm	6.0	5.7 mm
Implant System Compatibility	Implant Diameter (mm)	Platform Diameter																									
NobelActive®	3.0	3.0 mm																									
	3.5	NP (3.5 mm)																									
	4.3/5.0	RP (4.3 mm)																									
Straumann® Bone Level	3.3	NC (3.3 mm)																									
	4.1/4.8	RC (4.1 mm)																									
Neodent Implant System – GM Line	3.5 – 7.0	GM (Grand Morse)																									
Tapered Screw-Vent®	3.7 / 4.1	3.5 mm																									
	4.7	4.5 mm																									
	6.0	5.7 mm																									
Primary Predicate Device																											
K222215 IPD Dental Implant Abutments (Implant Prothesis Dental 2004, SL)	<p>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.</p> <p style="text-align: center;"><u>Compatible Implant Systems</u></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #D3D3D3;">Implant System Compatibility</th> <th style="background-color: #D3D3D3;">Implant Diameter (mm)</th> <th style="background-color: #D3D3D3;">Platform Diameter</th> </tr> </thead> <tbody> <tr> <td rowspan="3" style="text-align: center;">Brånemark</td> <td style="text-align: center;">3.5</td> <td style="text-align: center;">NP (3.5 mm)</td> </tr> <tr> <td style="text-align: center;">3.75 / 4.0</td> <td style="text-align: center;">RP (4.1 mm)</td> </tr> <tr> <td style="text-align: center;">5.0</td> <td style="text-align: center;">WP (5.1 mm)</td> </tr> <tr> <td rowspan="2" style="text-align: center;">Straumann® Tissue Level</td> <td style="text-align: center;">3.3 / 4.1 / 4.8</td> <td style="text-align: center;">RN (4.8 mm)</td> </tr> <tr> <td style="text-align: center;">4.8</td> <td style="text-align: center;">WN (6.5 mm)</td> </tr> <tr> <td rowspan="3" style="text-align: center;">Tapered Screw-Vent®</td> <td style="text-align: center;">3.7 / 4.1</td> <td style="text-align: center;">3.5 mm</td> </tr> <tr> <td style="text-align: center;">4.7</td> <td style="text-align: center;">4.5 mm</td> </tr> <tr> <td style="text-align: center;">6.0</td> <td style="text-align: center;">5.7 mm</td> </tr> </tbody> </table>		Implant System Compatibility	Implant Diameter (mm)	Platform Diameter	Brånemark	3.5	NP (3.5 mm)	3.75 / 4.0	RP (4.1 mm)	5.0	WP (5.1 mm)	Straumann® Tissue Level	3.3 / 4.1 / 4.8	RN (4.8 mm)	4.8	WN (6.5 mm)	Tapered Screw-Vent®	3.7 / 4.1	3.5 mm	4.7	4.5 mm	6.0	5.7 mm			
Implant System Compatibility	Implant Diameter (mm)	Platform Diameter																									
Brånemark	3.5	NP (3.5 mm)																									
	3.75 / 4.0	RP (4.1 mm)																									
	5.0	WP (5.1 mm)																									
Straumann® Tissue Level	3.3 / 4.1 / 4.8	RN (4.8 mm)																									
	4.8	WN (6.5 mm)																									
Tapered Screw-Vent®	3.7 / 4.1	3.5 mm																									
	4.7	4.5 mm																									
	6.0	5.7 mm																									

IPD Dental Implant Abutments
Traditional 510(k)

	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																																																																																					
K222288 DESS Dental Smart Solutions (Terrats Medical, SL)	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 Ti Base abutments or Pre-milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture.																																																																																				
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Compatible Implant System</th> <th style="text-align: center;">Implant Body Diameter, mm</th> <th style="text-align: center;">Implant Platform Name</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Ankylos C/X</td> <td style="text-align: center;">3.5, 4.5, 5.5</td> <td style="text-align: center;">2.52</td> </tr> <tr> <td rowspan="5" style="text-align: center;">Astra Tech EV</td> <td style="text-align: center;">3.0</td> <td style="text-align: center;">3.0</td> </tr> <tr> <td style="text-align: center;">3.6</td> <td style="text-align: center;">3.6</td> </tr> <tr> <td style="text-align: center;">4.2</td> <td style="text-align: center;">4.2</td> </tr> <tr> <td style="text-align: center;">4.8</td> <td style="text-align: center;">4.8</td> </tr> <tr> <td style="text-align: center;">5.4</td> <td style="text-align: center;">5.4</td> </tr> <tr> <td rowspan="2" style="text-align: center;">Astra Tech OsseoSpeed™</td> <td style="text-align: center;">3.0</td> <td style="text-align: center;">3.0</td> </tr> <tr> <td style="text-align: center;">3.5/4.0 4.5/5.0</td> <td style="text-align: center;">3.5/4.0 4.5/5.0</td> </tr> <tr> <td rowspan="4" style="text-align: center;">BioHorizons</td> <td style="text-align: center;">3.0, 3.4, 3.8</td> <td style="text-align: center;">3.0</td> </tr> <tr> <td style="text-align: center;">3.8, 4.6</td> <td style="text-align: center;">3.5</td> </tr> <tr> <td style="text-align: center;">4.6, 5.8</td> <td style="text-align: center;">4.5</td> </tr> <tr> <td style="text-align: center;">5.8</td> <td style="text-align: center;">5.7</td> </tr> <tr> <td rowspan="3" style="text-align: center;">Biomet 3i Certain®</td> <td style="text-align: center;">3.25</td> <td style="text-align: center;">3.4</td> </tr> <tr> <td style="text-align: center;">4.0</td> <td style="text-align: center;">4.1</td> </tr> <tr> <td style="text-align: center;">5.0</td> <td style="text-align: center;">5.0</td> </tr> <tr> <td rowspan="3" style="text-align: center;">Biomet 3i OSSEOTITE®</td> <td style="text-align: center;">3.25</td> <td style="text-align: center;">3.4</td> </tr> <tr> <td style="text-align: center;">3.75, 4.0</td> <td style="text-align: center;">4.1</td> </tr> <tr> <td style="text-align: center;">5.0</td> <td style="text-align: center;">5.0</td> </tr> <tr> <td rowspan="3" style="text-align: center;">Camlog</td> <td style="text-align: center;">3.8</td> <td style="text-align: center;">3.8</td> </tr> <tr> <td style="text-align: center;">4.3</td> <td style="text-align: center;">4.3</td> </tr> <tr> <td style="text-align: center;">5.0</td> <td style="text-align: center;">5.0</td> </tr> <tr> <td style="text-align: center;">Dentium SuperLine</td> <td style="text-align: center;">3.6, 4.0, 4.5, 5.0, 6.0, 7.0</td> <td style="text-align: center;">3.3</td> </tr> <tr> <td rowspan="4" style="text-align: center;">FRIADENT XiVE®</td> <td style="text-align: center;">3.4</td> <td style="text-align: center;">3.4</td> </tr> <tr> <td style="text-align: center;">3.8</td> <td style="text-align: center;">3.8</td> </tr> <tr> <td style="text-align: center;">4.5</td> <td style="text-align: center;">4.5</td> </tr> <tr> <td style="text-align: center;">5.5</td> <td style="text-align: center;">5.5</td> </tr> <tr> <td style="text-align: center;">MegaGen AnyRidge</td> <td style="text-align: center;">3.5, 4.0, 4.5, 5.0, 5.5</td> <td style="text-align: center;">3.5</td> </tr> <tr> <td style="text-align: center;">Neodent Grand Morse</td> <td style="text-align: center;">3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0</td> <td style="text-align: center;">Grand Morse (GM)</td> </tr> <tr> <td rowspan="3" style="text-align: center;">NobelActive®, NobelParallel Conical</td> <td style="text-align: center;">3.0</td> <td style="text-align: center;">3.0</td> </tr> <tr> <td style="text-align: center;">3.5</td> <td style="text-align: center;">NP</td> </tr> <tr> <td style="text-align: center;">4.3, 5.0</td> <td style="text-align: center;">RP</td> </tr> <tr> <td rowspan="3" style="text-align: center;">NobelReplace® Trilobe</td> <td style="text-align: center;">3.5</td> <td style="text-align: center;">NP</td> </tr> <tr> <td style="text-align: center;">4.3</td> <td style="text-align: center;">RP</td> </tr> <tr> <td style="text-align: center;">5.0</td> <td style="text-align: center;">WP</td> </tr> </tbody> </table>	Compatible Implant System	Implant Body Diameter, mm	Implant Platform Name	Ankylos C/X	3.5, 4.5, 5.5	2.52	Astra Tech EV	3.0	3.0	3.6	3.6	4.2	4.2	4.8	4.8	5.4	5.4	Astra Tech OsseoSpeed™	3.0	3.0	3.5/4.0 4.5/5.0	3.5/4.0 4.5/5.0	BioHorizons	3.0, 3.4, 3.8	3.0	3.8, 4.6	3.5	4.6, 5.8	4.5	5.8	5.7	Biomet 3i Certain®	3.25	3.4	4.0	4.1	5.0	5.0	Biomet 3i OSSEOTITE®	3.25	3.4	3.75, 4.0	4.1	5.0	5.0	Camlog	3.8	3.8	4.3	4.3	5.0	5.0	Dentium SuperLine	3.6, 4.0, 4.5, 5.0, 6.0, 7.0	3.3	FRIADENT XiVE®	3.4	3.4	3.8	3.8	4.5	4.5	5.5	5.5	MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5	Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)	NobelActive®, NobelParallel Conical	3.0	3.0	3.5	NP	4.3, 5.0	RP	NobelReplace® Trilobe	3.5	NP	4.3	RP	5.0	WP
	Compatible Implant System	Implant Body Diameter, mm	Implant Platform Name																																																																																		
	Ankylos C/X	3.5, 4.5, 5.5	2.52																																																																																		
	Astra Tech EV	3.0	3.0																																																																																		
		3.6	3.6																																																																																		
		4.2	4.2																																																																																		
		4.8	4.8																																																																																		
		5.4	5.4																																																																																		
	Astra Tech OsseoSpeed™	3.0	3.0																																																																																		
		3.5/4.0 4.5/5.0	3.5/4.0 4.5/5.0																																																																																		
	BioHorizons	3.0, 3.4, 3.8	3.0																																																																																		
		3.8, 4.6	3.5																																																																																		
		4.6, 5.8	4.5																																																																																		
		5.8	5.7																																																																																		
	Biomet 3i Certain®	3.25	3.4																																																																																		
		4.0	4.1																																																																																		
		5.0	5.0																																																																																		
	Biomet 3i OSSEOTITE®	3.25	3.4																																																																																		
		3.75, 4.0	4.1																																																																																		
5.0		5.0																																																																																			
Camlog	3.8	3.8																																																																																			
	4.3	4.3																																																																																			
	5.0	5.0																																																																																			
Dentium SuperLine	3.6, 4.0, 4.5, 5.0, 6.0, 7.0	3.3																																																																																			
FRIADENT XiVE®	3.4	3.4																																																																																			
	3.8	3.8																																																																																			
	4.5	4.5																																																																																			
	5.5	5.5																																																																																			
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5																																																																																			
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)																																																																																			
NobelActive®, NobelParallel Conical	3.0	3.0																																																																																			
	3.5	NP																																																																																			
	4.3, 5.0	RP																																																																																			
NobelReplace® Trilobe	3.5	NP																																																																																			
	4.3	RP																																																																																			
	5.0	WP																																																																																			

IPD Dental Implant Abutments
Traditional 510(k)

		6.0	6.0
		3.3	NP
	Nobel Brånemark System®	3.75, 4.0	RP
		5.0	WP
	Osstem TS	3.5	Mini
		4.0, 4.5, 5.0, 6.0, 7.0	Regular
	Straumann BLX	3.5, 3.75, 4.0, 4.5	RB
		5.0, 5.5, 6.5	WB
	Straumann® Bone Level	3.3	NC
		4.1/4.8	RC
	Straumann® Tissue Level	3.3	NNC, RN
		4.1	RN
		4.8	RN, WN
	Zimmer Eztetic	3.1	2.9
	Zimmer Screw Vent®/ Tapered Screw- Vent®	3.3, 3.7, 4.1	3.5
		4.7	4.5
		6.0	5.7
	Zimmer Spline	3.25	3.25
		3.75, 4.0	3.75/4.0
		5.0	5.0
	Zimmer SwissPlus	3.7	3.8
		4.8	4.8

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 new implant systems which IPD is claiming compatibility for this submission. 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:

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 in this submission.

As previously referred, differences may be found in the list of compatible implant systems for subject and predicate devices. Compatibility of the subject abutments with the specific OEM implants is based on engineering and dimensional analysis, as well as mechanical fatigue testing. In that sense, reference device, K222288, has been selected for the range of compatibility implant systems which encompasses and which IPD is citing compatibility by this submission.

Despite this, no differences are found in the device categories included for subject and predicate devices, and same approach is followed for finalizing the zirconia superstructures. Similarly, and thanks to the fatigue testing carried out and provided in this submission, the maximum angulation of the final abutment has been expanded. 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 5.3. Subject and Predicate devices technological characteristics comparison.

Characteristics	Subject Device IPD Dental Implant Abutments	Primary Predicate Device IPD Dental Implant Abutments (IMPLANT PROTESIS DENTAL 2004, S.L.) K222215	Reference Device DESS Dental Smart Solutions (Terrats Medical, SL) K222288
Materials			
Abutment Materials	Titanium Alloy Grade 5 (ISO 5832-3) + TiN or Anodized	Titanium Alloy Grade 5 (ISO 5832-3) + TiN or Anodized	Ti-6Al-4V ELI
Screw Materials	Titanium Alloy Grade 5 (ISO 5832-3) + TiN	Titanium Alloy Grade 5 (ISO 5832-3) + TiN	Ti-6Al-4V ELI DLC Coating
Superstructure	DD Bio Z Zirconia (K142987)	DD Bio Z Zirconia (K142987)	Zirconia conforming ISO 13356
General Design features			
Overview of abutment designs	Healing, Temporary, Cementing Titanium, Titanium interface	Healing, Temporary, Cementing Titanium, Titanium interface	Healing, Temporary Abutment, Ti Base, C- base, CrCo Base, Premilled Blank, Multi Unit Abutment, Multi Unit ZRN Abutment, DESSLoc
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, Multi-unit
Abutment / Implant Platform Diameter (mm)	3.0 – 5.7	3.5 – 6.5	2.52 – 6.5
Abutment Angle	Abutment: Straight (0°) Superstructure: Maximum Angulation 30°	Abutment: Straight (0°) Superstructure: Maximum Angulation 20°	0°, 17°, 30°
General Abutment / Implant Connection	Internal	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

IPD Dental Implant Abutments
Traditional 510(k)

Healing Abutments			
Characteristics	IPD (Subject device)	IPD Dental Implant Abutments (K222215)	DESS Dental Smart Solutions (K222288)
Min – Max diameter	3.0 – 5.7	3.5 - 5.1	2.52 – 5.7
Angle	Straight (0°)	Straight (0°)	Straight (0°)
Intended restoration type	Single-unit	Single-unit	Single-unit
Method of fixation	Screw-retained	Screw-retained	Screw-retained
Surface coating	Uncoated	Uncoated	Uncoated

Cementing and Temporary Abutments			
Characteristics	IPD Subject device	IPD Dental Implant Abutments (K222215)	DESS Dental Smart Solutions (K222288)
Min – Max diameter	3.0 – 4.3	3.5 – 6.5	2.52 – 5.7
Angle	Straight (0°)	Straight (0°)	Straight (0°)
Intended restoration type	Single-unit / Multi-unit	Single-unit / Multi-unit	Single-unit / Multi-unit
Method of fixation	Cement-retained / Screw-retained	Cement-retained / Screw-retained	Cement-retained / Screw-retained
Surface coating	Cementing: Uncoated Temporary: Anodized	Cementing: Uncoated Temporary: Anodized	Uncoated

Ti Base (Interface) Abutment			
Characteristics	IPD Subject device	IPD Dental Implant Abutments (K222215)	DESS Dental Smart Solutions (K222288)
Min – Max diameter	3.0 – 4.3	3.5 – 6.5	2.52 – 5.7
Intended restoration type	Single-unit / Multi-unit	Single-unit / Multi-unit	Single-unit / Multi-unit
Method of fixation	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained
Surface coating	TiN	TiN	Anodized

Superstructure Design			
Characteristics	IPD Subject device	IPD Dental Implant Abutments (K222215)	DESS Dental Smart Solutions (K222288)
Superstructure Design Workflow	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.	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.	All digitally designed custom abutments for use with Ti Base abutments or Pre-milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture.
Zirconia CAD/CAM Design Parameters – Ti (Base) Interface Abutment characteristics	Minimum Gingival height: 1.5 mm Minimum Wall Thickness: 0.43 mm Minimum Post Height: 4.75 mm Maximum Gingival Height: 6 mm Maximum Angulation: 30° (1)	Minimum Gingival height: 1.5 mm Minimum Wall Thickness: 0.43 mm Minimum Post Height: 4.75 mm Maximum Gingival Height: 6 mm Maximum Angulation: 20°	Minimum gingival height: 0.5 mm Minimum wall thickness: 0.4 mm Minimum post height: 4.2 mm Maximum gingival height: 6.0 mm Maximum Angulation: 20° / 30° (2)

Note 1: With the exception of Nobel Active® 3.0 and 3.5 mm-platforms which final abutment is straight (0°).

Note 2: Design parameters for Ti Base Interface compatible with Biomet 3i Certain, NobelReplace Trilobe, and Zimmer Screw-Vent/Tapered Screw-Vent (except for 3.3 mm implants).

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 the same materials and surface coatings;
- It is sterilized using the same processes.

Ti Base (Interface) 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.

Device categories, materials and technological characteristics of the subject device are almost identical with previously cleared IPD Dental Implant Abutments (predicate device). Subject and predicate devices are very similar in design, with differences on the expanded compatibilized OEM dental implant systems for IPD Dental Implant Abutments and the increased maximum angulation of the final abutment (design parameters for the zirconia superstructure) thanks to the verifications performed by fatigue testing included in this submission.

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 Skin sensitization and Irritation Testing according to ISO 10993-10 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

IPD Dental Implant Abutments

Traditional 510(k)

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 K222215, previously cleared, 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 and materials and similar technological characteristics. The subject device and the predicate and reference devices encompass the same range of device categories, similar (OEM implant dependent) diameters, and almost identical designs. The subject and predicate device are produced using identical materials and surface coatings, as well as 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, we conclude that the data included in the submission demonstrate that the subject device, IPD Dental Implant Abutments, is substantially equivalent to the predicate devices.