10/21/2022

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

Re: K222215
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 19, 2022
Received: July 25, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Andrew 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222215

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
Brånemark	3.5 3.75 / 4.0 5.0	NP (3.5 mm) RP (4.1 mm) WP (5.1 mm)
Straumann® Tissue Level	3.3 / 4.1 / 4.8 4.8	RN (4.8 mm) WN (6.5 mm)
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.

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
Camí del Mig, 71. 1º 2ª
08302 Mataró (Barcelona), Spain.

Contact Person:
Francesc Fumanal
+34 93 672 110 748
ffumanal@ipd2004.com

Date prepared: October 21, 2022.

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:	K201860 Elos Accurate® Hybrid Base™
Reference Devices:	K170588 DESS Dental Smart Solutions
	K153521 IH Implant System
	K173908 DESS Dental Smart Solutions

Compatible Implant Systems		
Clearance	**Device**	**Manufacturer**
K022562	Brånemark	Nobel Biocare AB
K130222	Straumann® Tissue Level	Institut Straumann AG
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"*.

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			
Brånemark	External	3.5 3.75 / 4.0 5.0	NP (3.5 mm) RP (4.1 mm) WP (5.1 mm)	AA	3.5 4.1 5.1	3.5 4.1 5.1	3.5 4.1 5.1
Straumann® Tissue Level	Internal	3.3/4.1/4.8 4.8	RN (4.8 mm) WN (6.5 mm)	DA	4.8	4.8 6.5	4.8 6.5
Tapered Screw-Vent®	Internal	3.7 / 4.1 4.7 6.0	3.5 mm 4.5 mm 5.7 mm	FA	3.5 4.5	3.5 4.5 5.7	3.5 4.5 5.7

The abovementioned Compatible Implant Systems received FDA-clearance with the following 510(k) concurrence numbers: Brånemark K022562 (*aka* Various Brånemark System Dental Implant Products); Straumann® Tissue Level K130222 (*aka* ITI Synocta Meso Abutments), 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
Maximum angulation (Occlusal channel)	20°

All CAD/CAM superstructures are for straight abutments only.

The laboratory designed superstructure is attached to Ti Base (Interface) by the use of an FDA-cleared cement (i.e. 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
Brånemark	3.5 3.75 / 4.0 5.0	NP (3.5 mm) RP (4.1 mm) WP (5.1 mm)
Straumann® Tissue Level	3.3 / 4.1 / 4.8 4.8	RN (4.8 mm) WN (6.5 mm)
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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

Table 5.2. Indications for Use Statements.

<table>
<tr><th colspan="2">Indications for Use Statements</th></tr>
<tr><td colspan="2">Subject device</td></tr>
<tr><td>IPD Dental Implant Abutments (Implant Protesis Dental 2004 SL)</td><td>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.

<u>Compatible Implant Systems</u>

<table>
<tr><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter</th></tr>
<tr><td>Brånemark</td><td>3.5
3.75 / 4.0
5.0</td><td>NP (3.5 mm)
RP (4.1 mm)
WP (5.1 mm)</td></tr>
<tr><td>Straumann® Tissue Level</td><td>3.3 / 4.1 / 4.8
4.8</td><td>RN (4.8 mm)
WN (6.5 mm)</td></tr>
<tr><td>Tapered Screw-Vent®</td><td>3.7 / 4.1
4.7
6.0</td><td>3.5 mm
4.5 mm
5.7 mm</td></tr>
</table>

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.</td></tr>
<tr><td colspan="2">Primary Predicate Device</td></tr>
<tr><td>K201860
Elos Accurate® Hybrid Base™</td><td>The Elos Accurate® Hybrid Base™ is intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Hyblid Base™ is used as an interface between a dental implant and a zirconia superstructure and will be attached to the implant using a prosthetic screw and attached to the zirconia superstructure by cementing. The Elos Accurate® Hybrid Base™ is compatible with the implant systems listed in table l:

Table 1.
<table>
<tr><th>Implant Platform compatibility</th><th>Platform diameter [mm]</th><th>Implant Body diameter [mm]</th></tr>
<tr><td>Nobel Replace NP</td><td>3.5</td><td>3.5</td></tr>
<tr><td>Nobel Replace RP</td><td>4.3</td><td>4.3</td></tr>
</table></td></tr>
</table>

		Nobel Replace WP	5	5
		Nobel Replace 6.0	6	6
		Nobel CC 3.0	3	3
		Nobel CC NP	3.5	3.5 & 3.75
		Nobel CC RP	3.9	4.3 & 5
		Nobel CC WP	5.1	5.5
		Straumann Bone Level NC	3.3	3.3
		Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8
		Astra Tech 3.0	3	3
		Astra Tech 3.5/4.0	3.5 & 4	3.5 & 4
		Astra Tech 4.5/5.0	4.5 & 5	4.5 & 5
		Astra Tech EV 3.0	3	3
		Astra Tech EV 3.6	3.6	3.6
		Astra Tech EV 4.2	4.2	3.6 & 4.2
		Astra Tech EV 4.8	4.8	4.2 & 4.8
		Astra Tech EV 5.4	5.4	5.4
		Brånemark NP	3.5	3.3
		Brånemark RP	4.1	3.75, 4 & 5
		Brånemark WP	5.1	5 & 6
	The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ 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 Devices				
K170588 DESS Dental Smart Solutions (Terrats Medical)	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. **Compatible Implant Systems**			

<table>
<tr><td></td><td></td><td>
<table>
<tr><th>Compatible Implant System</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr>
<tr><td>3i Certain®</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>3i OSSEOTITE®</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>OsseoSpeedTM</td><td>3.5, 4.0, 5.0</td><td>3.5/4.0, 4.5/5.0</td></tr>
<tr><td>FRIADENT XiVE</td><td>3.4, 3.8, 4.5</td><td>3.4, 3.8, 4.5</td></tr>
<tr><td>NobelActive®</td><td>3.5, 4.3, 5.0</td><td>NP, RP</td></tr>
<tr><td>NobelReplace Conical</td><td>3.5, 4.3, 5.0</td><td>NP, RP</td></tr>
<tr><td>Nobel Replace Trilobe</td><td>3.5, 4.3, 5.0</td><td>NP, RP, WP</td></tr>
<tr><td>Brånemark</td><td>3.5, 3.75/4.0, 5.0</td><td>NP, RP, WP</td></tr>
<tr><td>Straumann® Bone Level</td><td>3.3, 4.1, 4.8</td><td>NC, RC</td></tr>
<tr><td>Straumann® Tissue Level</td><td>3.3, 4.1, 4.8</td><td>RN, WN</td></tr>
<tr><td>Tapered Screw-Vent®</td><td>3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
</table>
</td></tr>
<tr><td>K153521
IH Implant System (Sewonmedix)</td><td colspan="2">IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained or screw retained restorations and terminal or interminal abutment support for fixed bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.</td></tr>
<tr><td>K173908
DESS Dental Smart Solutions (Terrats Medical)</td><td colspan="2">DESS Dental Smart Solutions 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 Aurum™ Abutment or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture.
Compatible Implant Systems
<table>
<tr><th>Implant System Compatibility</th><th>Implant Body</th><th>Implant Platform</th></tr>
<tr><td>3i Certain®</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>3i OSSEOTITE®</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>OsseoSpeed™</td><td>3.5, 4.0, 5.0</td><td>3.5/4.0, 4.5/5.0</td></tr>
<tr><td>FRIADENT XiVE</td><td>3.4, 3.8, 4.5</td><td>3.4, 3.8, 4.5</td></tr>
<tr><td>NobelActive®</td><td>3.5, 4.3, 5.0</td><td>NP, RP</td></tr>
<tr><td>NobelReplace® Conical</td><td>3.5, 4.3, 5.0</td><td>NP, RP</td></tr>
<tr><td>NobelReplace® Trilobe</td><td>3.5, 4.3, 5.0</td><td>NP, RP, WP</td></tr>
<tr><td>Branemark</td><td>3.5, 3.75/4.0, 5.0</td><td>NP, RP, WP</td></tr>
<tr><td>Straumann® Bone Level</td><td>3.3, 4.1, 4.8</td><td>NC, RC</td></tr>
<tr><td>Straumann® Tissue Level</td><td>3.3, 4.1, 4.8</td><td>RN, WN</td></tr>
<tr><td>Tapered Screw-Vent®</td><td>3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
</table>
</td></tr>
</table>

Discussion on Indications for Use:

Although there has been some change in the wording used to describe the indications for use statement in comparison with predicate devices to adapt to subject device, it is considered that there has been no change in the intended use or indications for use of the IPD Dental Implant Abutments. The devices are specifically indicated for patients undergoing oral implant surgery to provide support for dental prosthetic restorations.

When comparing the indications for use statements for the subject device and primary predicate device (K201860) together with reference predicate (K170588), it is observed that all are dental abutment systems that are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic support for dental prosthetic restorations (single or multiple) as rehabilitation of edentulous maxilla and mandibles.

Primary predicate K201860 refers to a specific type of abutment (Hybrid Base) to be used as an interface between the dental implant and a cemented zirconia superstructure, whereas subject device refers to IPD specific abutment. It is interesting to observe that reference predicates (K170588 and K153521) refer to other types of dental abutments, as IPD do, in that sense, differences may be found on the digital dentistry workflow selected for the reference predicate (K170588 or K173908) by the use of validated milling centers versus the definition of the digital workflow system. Information on the software tools to be used to enable the user to digitally design custom abutments within appropriate limits and to produce them (either at the point of care or at a dental laboratory selected by the user) has been included in this submission.

In regard to reference predicate K153521, due to the combination of dental implants and abutments, the intended use is mainly focused on dental implant indications for use, although dental abutments indications are also referenced.

For the subject device, the design and fabrication of the superstructure is conducted using a 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.

Likewise, differences may be found in the list of compatible implant systems. Compatibility of the subject abutments with the specific OEM implants listed for the subject device is based on engineering and dimensional analysis, as well as mechanical fatigue testing, as previously referenced.

Nevertheless, no differences further than device categories included in each of the selected primary or reference predicates, the approach followed for finalizing the zirconia superstructures or claimed OEM implant systems compatibility, have been observed. 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 device technological characteristics comparison.

Characteristics	**Subject Device** IPD Dental Implant Abutments	**Primary Predicate Device** Elos Accurate® Hybrid Base™ (Elos Medtech Pinol) K201860	**Reference Device** DESS Dental Smart Solutions (Terrats) K170588	**Reference Device** IH Implant System (Sewon medix) K153521	**Reference Device** DESS Dental Smart Solutions (Terrats) K173908
Materials					
Abutment Materials	Titanium Alloy Grade 5 (per ISO 5832-3) + TiN or Anodized	Ti-6Al-4V alloy (Anodized, non-anodized)	Ti-6Al-4V + ZrN	Titanium Alloy (ASTM F 136) / Pure Titanium Gr. 4 (ASTMF67-06) + TiN	Titanium Alloy CoCr, Zirconia
Screw Materials	Titanium Alloy Grade 5 (per ISO 5832-3) + TiN	Ti-6Al-4V alloy (ASTM Fl36) (Medicarb/DLC coating)	Ti-6Al-4V alloy + DLC	Not available in the 510(k) summary.	Titanium Alloy
Superstructure	DD Bio Z Zirconia (K142987)	3M Lava Plus Zirconia (K011394)	Not available in the 510(k) summary.	Not included.	Not available in the 510(k) summary.
General Design features					
Overview of abutment designs	Healing, Temporary, Cementing Titanium, Titanium interface	Hybrid Base (2 piece – zirconia bonded to hybrid base mounted on to the implant and fixed with a screw)	Healing, Temporary, Straight, Ti bases, Pre-milled Blank, DESSLOC (Locator-type),	Healing, Temporary, Cement, Solid, Angled, Multi-unit, FreeMilling	CAD/CAM Blank CAD/CAM TiBase Castable Abutment Aurum Abutment

			Multi-Unit		
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained
Restoration Type	Single-unit (crowns) Multiple-unit (bridges)	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Abutment / Implant Platform Diameter (mm)	3.5 – 6.5	3.0 – 6.0	3.5 – 6.5	4.0 – 7.0	3.4 – 6.5
Abutment Angle	Abutment: Straight (0º) Superstructure: Maximum Angulation 20º	Maximum: 20°	Straight	Angled: 15°/25° Multi-unit Angled: 17°/30°	Straight (0º)
General Abutment / Implant Connection	Internal and External	Internal and External	Internal and External	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	IH Prosthetic System: Non-sterile. End user steam sterilization	Non-sterile. End user steam sterilization

Healing Abutments		
Characteristics	**IPD (Subject device)**	**DESS Dental Smart Solutions (K170588)**
Min – Max diameter	3.5 - 5.1	3.5 - 6.5
Angle	Straight (0°)	Straight (0°)
Intended restoration type	Single-unit	Single-unit
Method of fixation	Screw-retained	Screw-retained

Cementing and Temporary Abutments			
Characteristics	**IPD** Subject device	**DESS Dental Smart Solutions (K170588)**	**IH Implant System (K153521)**
Min – Max diameter	3.5 – 6.5	3.5 – 6.5	Cement: 4.5 - 6.5 Temporary: 4.0 - 4.5
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	Uncoated	Temporary: Uncoated. Cement: TiN

Ti interface Abutment				
Characteristics	**IPD** Subject device	**Elos Accurate Hybrid Base (K201860)**	**DESS Dental Smart Solutions (K170588)**	**IH Implant System (K153521)**
Min – Max diameter	3.5 – 6.5	3.5 - 5.1	3.5 – 6.5	Solid: 4.0 - 7.0
Angle	Straight (0°)	Max. 20°	Straight	Straight
Intended restoration type	Single-unit Multi-unit	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	Cement-retained Screw-retained
Surface coating	TiN	Anodized	Uncoated	TiN

Superstructure Design [1]			
Characteristics	**IPD Subject device**	**Elos Accurate Hybrid Base (K201860)**	**DESS Dental Smart Solutions (K173908)**
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 zirconia superstructures for use with the Elos Accurate® Hybrid Base™ 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 Aurum™ Abutment or Pre-milled Blank 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: 20º	Gingival height: Not stated. Minimal Wall Thickness: 0.5 mm Minimum Post Height: 4.0 mm (for single unit restorations) Maximum Gingival Height: 5.0 mm Maximum Angulation: 20º	Gingival height: Not stated Minimal Wall Thickness: 0.4 mm Minimum Post Height: 4.0 mm Maximum Gingival Height: 6.0 mm Angulation: 0º (for straight abutments only)

[1] Please note that K153521 has not been included in the comparison as no reference to CAD/CAM technology is included in the 510(k) Summary.

The data included in this submission demonstrate substantial equivalence to the primary and/or reference predicate devices listed above. 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 basic design and device categories;
- Incorporates the same or similar 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.

Reference devices K170588 and K173908 refer to custom abutments intended to be used in a digital dentistry workflow but to be sent to a validated milling center for design and manufacture. Despite this, they are similar in design, device categories, materials and technological characteristics to those proposed of the subject device and just some differences in terms of surface coatings solutions applied are found, which may be covered by the secondary reference device K153521, like TiN coating. Hence, Reference devices K170588, K173908 and K153521 account for the differences in device categories and surface coatings compared to Primary Predicate K201860 to support substantial equivalence.

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 abutments and screws 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.
- 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 Implant Abutments.

Non-clinical performance testing showed that IPD abutments and screws 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 have similar technological characteristics. The subject device and the predicate and reference devices encompass the same range of device categories, diameters, and similar designs. The subject and predicate and reference devices are produced using similar materials and surface coatings, as well as fabrication processes, and are to be sterilized by the user using similar 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 device.