Elos Medtech Pinol A/S
Lise Terkelsen
Regulatory Affairs Professional
Engvej 33
Goerloese, 3330
DENMARK

September 13, 2024

Re: K241722
Trade/Device Name: Elos Accurate® Hybrid Base™; Elos Accurate® Customized Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: June 14, 2024
Received: June 14, 2024

Dear Lise Terkelsen:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241722

Device Name

Elos Accurate Hybrid Base;
Elos Accurate Customized Abutment

Indications for Use *(Describe)*

Elos Accurate Hybrid Base

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 Hybrid 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 1:

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Straumann BLX RB/ WB	Ø3.4/Ø3.5/Ø4.5	Ø3.5/Ø3.75/Ø4/Ø4.5/Ø5/Ø5.5/Ø6.5

The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are either intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility or 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.

Elos Accurate Customized Abutment

The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.

The Elos Accurate® Customized Abutment is compatible with the implant systems listed in table 1:

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Straumann BLX RB/ WB	Ø3.4/Ø3.5/Ø4.5	Ø3.5/Ø3.75/Ø4/Ø4.5/Ø5/Ø5.5/Ø6.5
Astra Tech 3.0	Ø3.	Ø3
Astra Tech EV 3.0	Ø3	Ø3

All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments are either intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility or 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, 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.

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510(k) Summary K241722
Elos Accurate® Hybrid Base™, Elos Accurate® Customized Abutment
September 13, 2024

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR § 807.92.

I. Company:

Elos Medtech Pinol A/S
Engvej 33
DK-3330 Goerloese
Denmark

Contacts:

Lise Terkelsen
Regulatory Affairs Professional
Tel: +45 21 61 12 25
E-mail: lise.terkelsen@elosmedtech.com

Søren Rangstrup
Manager of Product Development & Regulatory Affairs
Tel: +45 20 66 64 42
E-mail: soren.rangstrup@elosmedtech.com

II. Proprietary Trade Name: Elos Accurate® Hybrid Base™
Elos Accurate® Customized Abutment

III. Classification Name: Endosseous Dental Implant Abutment

IV. Classification: Class II, 21 CFR 872.3630

V. Product Code(s): NHA as the primary product code
PNP as the secondary product code

VI. Identification of Legally Marketed Devices:

The design features, materials and Indications for Use of the subject devices are substantially equivalent to the predicate device noted below.

Primary Predicate Device:

- K230317 / SE 09/01/2023 - Elos Accurate® Hybrid Base™

Reference Devices:

- K231307 / SE 12/21/2023 - Elos Accurate® Customized Abutment
- K151455 / SE 06/09/2016 - 3Shape Abutment Designer Software
- K173961 / SE 06/05/2018 – Straumann BLX Implant System
- K181703 / SE 12/28/2018 – Straumann BLX Line Extension - Implants, SRAs and Anatomic Abutment
- K191256 / SE 12/27/2019 – Straumann BLX Ø3.5 mm Implants

- K080396 / SE 04/30/2008 – OSSEOSPEED NARROW
- K120414 / SE 07/31/2012 – OSSEOSPEED PLUS

VII. Product Description:

The Elos Accurate® Customized Abutment and Elos Accurate® Hybrid Base™ are both patient-specific components designed for attaching to dental implants, providing a basis for single or multiple tooth prosthetic restorations.

The Elos Accurate® Customized Abutment and Elos Accurate® Hybrid Base™ will be attached to the implant using the included Elos Prosthetic Screw.

The Elos Accurate® Hybrid Base™ is a two-piece abutment composed of the pre-manufactured prosthetic component, the Hybrid Base in Titanium alloy per ASTM F136, as the bottom-half, and the zirconia superstructure as the top-half, which the laboratory/clinic is designing by use of the 510(k) cleared design software (3Shape Abutment Designer™ Software, K151455), which when assembled comprises the final finished medical device. The laboratory designed superstructure is manufactured from 510(k) cleared Zirconia (Lava Plus, K011394) according to digital dentistry workflow. The laboratory designed superstructure is attached to the Elos Accurate® Hybrid Base by use of 510(k) cleared cement (Multilink Hybrid Abutment, K130436 or Panavia V5, K150704)

While the Elos Accurate® Customized Abutment is a one-piece abutment which consists of an Abutment Blank used in fabricating of a full patient-specific abutment in Titanium alloy per ASTM F136. The Abutment Blank used in creation of the Elos Accurate® Customized Abutment has a pre-manufactured connection interface that fits directly to a pre-specified dental implant. The same applies to the Elos Accurate® Hybrid Base™ which fits directly to an endosseous dental implant. The customized shape of the abutment is intended to be manufactured according to a digital dentistry workflow or intended to be manufactured at an FDA registered Elos Medtech approved milling facility.

The Elos Accurate library files for both Elos Accurate® Customized Abutment and Elos Accurate® Hybrid Base™ have built-in design limitations, and the user isn't allowed to exceed these limitations as follows:

Customized Abutments:	Hybrid Base abutments (zirconia part):
Min. wall thickness 0.4 mm	Min. wall thickness 0.5 mm
Gingival height min. 0.5mm or max. 5 mm	Gingival height min. 0.5mm or max. 5 mm
Max. angulation 20° or 30°.	Max. angulation 20°.
Min. post height* 4 mm	Min. post height* 4 mm

*The post height is defined as the cementable height of the abutment.

The Elos Accurate® Customized Abutment and the Elos Accurate® Hybrid Base™ are both delivered non-sterile and the final restoration including corresponding Elos Prosthetic Screw is intended to be sterilized at the dental clinic before it is placed in the patient.

VIII. Indications for Use:

Customized Abutment

The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.

The Elos Accurate® Customized Abutments are compatible with the implant systems listed in Table 1:

Table 1.

Implant Platform compatibility	**Platform diameter [mm]**	**Implant Body diameter [mm]**
Straumann BLX RB/ WB	Ø3.4/Ø3.5/Ø4.5	Ø3.5/Ø3.75/Ø4/Ø4.5/Ø5/Ø5.5/Ø6.5
Astra Tech 3.0	Ø3.	Ø3
Astra Tech EV 3.0	Ø3	Ø3

All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments are either intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility or 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, milling machine and associated tooling and accessories.

Hybrid Base

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 Hybrid 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 1:

Table 1.

Implant Platform compatibility	**Platform diameter [mm]**	**Implant Body diameter [mm]**
Straumann BLX RB/ WB	Ø3.4/Ø3.5/Ø4.5	Ø3.5/Ø3.75/Ø4/Ø4.5/Ø5/Ø5.5/Ø6.5

The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are either intended to be sent and manufactured at an FDA registered Elos Medtech approved milling facility or 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.

IX. Summary of the Technological Characteristics:

The subject devices provide additional restorative options for connection to existing implant platforms. The subject devices have similar Indications for Use, intended use, designs, sizes and configurations, materials, and principles of operation as the predicate device. In order to determine nominal dimensions and tolerances of the Elos Accurate® Hybrid Base™ and Elos Accurate® Customized Abutment products, measuring- and dimensional analyses of original manufacturers' components (abutments, implants & abutment screws) have been made.

Comparing to the primary predicate device, the specific language (wording) of the Indications for Use Statements is identical except for implant system compatibility. The implant system

compatibility of the subject device is extended to include compatibility to the Straumann BLX and Astra Tech EV Implant system platforms for Customized Abutment and Straumann BLX for Hybrid Base. The difference in implant system compatibility is substantiated by engineering and dimensional analysis of original manufactures' components (abutments, implants & abutment screws) for determination of compatibility and new fatigue testing.

The approach of designing and manufacturing the Customized Abutment or zirconia superstructure (Hybrid Base) for the subject device is either according to a digital dentistry workflow or to be sent and manufactured at an FDA registered Elos Medtech approved milling facility (identical to Primary Predicate Device K230317). The subject device does not represent any new worst case, and is thereby covered by existing workflow validation submitted in K230317 and K231307, except the additional new digital libraries were validated as part of the subject submission, which included following:

- Scanner: 3Shape scanner (accuracy >10µm)
- Design library file (DME-file) provided by Elos Medtech which includes design limits in accordance with "Instruction For Use"
- Design Software: 3Shape Abutment Designer Software (K151455)
- Milling Unit: CORiTEC, imes-icore milling unit

- Zirconia Material: 3M Lava Plus Zirconia (K011394) **(only relevant for Elos Accurate Hybrid Base)**
- Adhesive material: Multilink Hybrid Abutment Cement, Ivoclar Vivadent AG (K130436) or Panavia V5 by KURARAY NORITAKE DENTAL (K150704) **(only relevant for Elos Accurate Hybrid Base)**

Indications for Use
Subject Device

Elos Accurate® Customized Abutment

The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.
The Elos Accurate® Customized Abutment is compatible with the implant systems listed in table 1:

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Straumann BLX RB/WB	Ø3.4/Ø3.5/Ø4.5	Ø3.5/Ø3.75/Ø4/Ø4.5/Ø5/Ø5.5/Ø6.5
Astra Tech 3.0	Ø3	Ø3
Astra Tech EV 3.0	Ø3	Ø3

All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments are either intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility or 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, milling machine and associated tooling and accessories.

Indications for Use
Reference Device (K231307)

Elos Accurate® Customized Abutment

The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.
The Elos Accurate® Customized Abutments are compatible with the implant systems listed in table 1:

Table 1.

Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Zimmer Screw-vent 3.5	Ø3.5	Ø3.7/Ø4.1
Zimmer Screw-vent 4.5	Ø4.5	Ø4.7
Zimmer Screw-vent 5.7	Ø5.7	Ø6.0
Biomet 3i Certain 3.4	Ø3.4	Ø3.25
Biomet 3i Certain 4.1	Ø4.1	Ø4
Biomet 3i Certain 5.0	Ø5	Ø5
Biomet 3i Certain 6.0	Ø6	Ø6
Straumann Standard RN	Ø4.8	Ø3.3/Ø4.1/Ø4.8
Straumann Standard WN	Ø6.5	Ø4.8
Neodent GM	Ø3.5/Ø4.5/Ø5.5/Ø 6.5	Ø3.5/Ø3.75/Ø4/Ø4.3/Ø 5/Ø 6/Ø 7
Hiossen ET Mini	Ø3.2/Ø3.5	Ø3.2/Ø3.5

Indications for Use
Subject Device

Elos Accurate® Hybrid Base™

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 Hybrid 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 1:

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Straumann BLX RB/WB	Ø3.4/Ø3.5/Ø4.5	Ø3.5/Ø3.75/Ø4/Ø4.5/Ø5/Ø5.5/Ø6.5

The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are either intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility or 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.

Indications for Use
Primary Predicate Device (K230317)

Elos Accurate® Hybrid Base™

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 Hybrid 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 1:

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Zimmer Screw-vent 3.5	Ø3.5	Ø3.7/Ø4.1
Zimmer Screw-vent 4.5	Ø4.5	Ø4.7
Zimmer Screw-vent 5.7	Ø5.7	Ø6.0
Biomet 3i Certain 3.4	Ø3.4	Ø3.25
Biomet 3i Certain 4.1	Ø4.1	Ø4
Biomet 3i Certain 5.0	Ø5	Ø5
Biomet 3i Certain 6.0	Ø6	Ø6
Straumann Standard RN	Ø4.8	Ø3.3/Ø4.1/Ø4.8
Straumann Standard WN	Ø6.5	Ø4.8
Neodent GM	Ø3.5/Ø4.5/Ø5.5/Ø 6.5	Ø3.5/Ø3.75/Ø4/Ø4.3/Ø 5/Ø 6/Ø 7
Hiossen ET Mini	Ø3.2/Ø3.5	Ø3.2/Ø3.5

Discussion

The Indication for use for the subject device is similar to the Primary Predicate Device, beside table 1. which have been replaced with for Customized Abutment 3 new implant systems and for Hybrid Base 1 new implant system, and the approach for finalizing the zirconia superstructure is the same.

The difference in implant system compatibility is substantiated by engineering and dimensional analysis of original manufactures' components (abutments, implants & screws) for determination of compatibility and new fatigue testing.

	Hiossen ET Regular | Ø4/Ø4.5/Ø5 / Ø5.5/Ø6/Ø7 | Ø4/Ø4.5/Ø5/ Ø5.5/Ø6/Ø7 All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments are either intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility or 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, milling machine and associated tooling and accessories.		Hiossen ET Regular | Ø4/Ø4.5/Ø5/ Ø5.5/Ø6/Ø | Ø4/Ø4.5/Ø5/ Ø5.5/Ø6/Ø7 The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are either intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility or 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.	

Element of Comparison	**Subject Device** **Elos Accurate® Customized Abutment** Elos Medtech Pinol A/S	**Reference device K231307** **Elos Accurate® Customized Abutment** Elos Medtech Pinol A/S	**Subject Device** **Elos Accurate® Hybrid Base™** Elos Medtech Pinol A/S	**Primary Predicate Device K230317** **Elos Accurate® Hybrid Base™** Elos Medtech Pinol A/S	**Discussion**
Intended Use	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function	Substantial equivalent
Reason for Predicate/Reference	Not applicable	Indication for Use, Abutment Design and manufacturing workflow	Not applicable	Indication for Use, Abutment Design and manufacturing workflow	N/A
Abutment Designs	1 piece – abutment mounted on to the implant and fixed with a screw	1 piece – abutment mounted on to the implant and fixed with a screw	2 piece – zirconia bonded to hybrid base mounted on to the implant and fixed with a screw	2 piece – zirconia bonded to hybrid base mounted on to the implant and fixed with a screw	Substantial equivalent
Prosthesis Attachment	Abutment screw-retained to implant	Abutment screw-retained to implant	Abutment screw-retained to implant Superstructure cement-retained	Abutment screw-retained to implant Superstructure cement-retained	Customized Abutments are substantial equivalent. Hybrid Bases are substantial equivalent.
Restoration	Single-unit	Single-unit	Single-unit Multi-unit	Single-unit Multi-unit	Customized Abutments are substantial equivalent. Hybrid Bases are substantial equivalent.
Abutment/Implant	3.0 – 4.5	3.2 – 7.0	3.4 – 4.5	3.2 – 7.0	Customized Abutment: Implant diameter for the

Element of Comparison	**Subject Device** **Elos Accurate® Customized Abutment** Elos Medtech Pinol A/S	**Reference device K231307** **Elos Accurate® Customized Abutment** Elos Medtech Pinol A/S	**Subject Device** **Elos Accurate® Hybrid Base™** Elos Medtech Pinol A/S	**Primary Predicate Device K230317** **Elos Accurate® Hybrid Base™** Elos Medtech Pinol A/S	**Discussion**
Platform Diameter (mm)					subject device is down to 3.0mm, which is smaller than the primary predicate device. The Mechanical perfomance of the 3 mm diameter components for both AstraTech & AstraTech EV is demonstrated in fatigue testing. Hybrid Base: Substantial equivalent as Implant diameter for the subject device is within the range of the Primary Predicate Device K230317
Abutment Angle	AstraTech 3.0: Up to 20° AstraTech EV 3.0: Up to 20° Straumann BLX: Up to 30°	Up to 30°	20° maximum	20° maximum	Customized Abutment: Substantial equivalent, as the max angulation is within the value used for Reference Device K231307. Hybrid Base: Substantial equivalent
Gingival Height	Up to 5 mm	Up to 5 mm	Up to 5 mm	Up to 5 mm	Substantial equivalent
Materials					
Abutment	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Substantial equivalent
Screw	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Substantial equivalent
Zirconia superstructure			3M Lava zirconia	3M Lava zirconia	Substantial equivalent
Surface	Abutment: Non-coated Screw: Non-coated,	Abutment: Non-coated Screw: Non-coated,	Abutment: Anodized	Abutment: Anodized	The surface of the Subject Abutment & screw is

Element of Comparison	**Subject Device** **Elos Accurate® Customized Abutment** Elos Medtech Pinol A/S	**Reference device K231307** **Elos Accurate® Customized Abutment** Elos Medtech Pinol A/S	**Subject Device** **Elos Accurate® Hybrid Base™** Elos Medtech Pinol A/S	**Primary Predicate Device K230317** **Elos Accurate® Hybrid Base™** Elos Medtech Pinol A/S	**Discussion**
		Medicarb coating	Screw: Non-coated	Screw: Non-coated, Medicarb coated	Substantial equivalent to Primary Predicate Device K230317. Mechanical perfomance is demonstrated in fatigue testing.
Design Workflow	3Shape intra oral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455	3Shape intra oral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455	3Shape intra oral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455	3Shape intra oral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455	Substantial equivalent
Manufacturing Workflow	CORiTEC milling unit (imes-icore)	CORiTEC milling unit (imes-icore)	CORiTEC milling unit (Imes-Icore)	CORiTEC milling unit (imes-icore)	Substantial equivalent
Adhesive material			Multilink Hybrid Abutment Cement, Ivoclar Vivadent AG (K130436) or Panavia V5 by KURARAY NORITAKE DENTAL (K150704)	Multilink Hybrid Abutment Cement, Ivoclar Vivadent AG (K130436) or Panavia V5 by KURARAY NORITAKE DENTAL (K150704)	Substantial equivalent
Sterilization	The recommended sterilization procedure is full cycle pre-vacuum steam sterilization at a temperature of 132 °C	The recommended sterilization procedure is full cycle pre-vacuum steam sterilization at a temperature of 132 °C (270˚F) for 4	The recommended sterilization procedure is full cycle pre-vacuum steam sterilization at a temperature of 132 °C	The recommended sterilization procedure is full cycle pre-vacuum steam sterilization at a temperature of 132 °C	Substantial equivalent

Element of Comparison	Subject Device Elos Accurate® Customized Abutment Elos Medtech Pinol A/S	Reference device K231307 Elos Accurate® Customized Abutment Elos Medtech Pinol A/S	Subject Device Elos Accurate® Hybrid Base™ Elos Medtech Pinol A/S	Primary Predicate Device K230317 Elos Accurate® Hybrid Base™ Elos Medtech Pinol A/S	Discussion
	(270˚F) for 4 minutes. Dry time: 20 minutes.	minutes. Dry time: 20 minutes.	(270˚F) for 4 minutes. Dry time: 20 minutes	(270˚F) for 4 minutes. Dry time: 20 minutes	
Operating principle	The primary function is to connect the dental implant (which is anchored in the jawbone) to the prosthetic crown or bridge. After an implant has osseointegrated, the abutment is screwed into the implant. It provides the foundation onto which the prosthetic tooth is attached.	The primary function is to connect the dental implant (which is anchored in the jawbone) to the prosthetic crown or bridge. After an implant has osseointegrated, the abutment is screwed into the implant. It provides the foundation onto which the prosthetic tooth is attached.	The primary function is to connect the dental implant (which is anchored in the jawbone) to the prosthetic crown or bridge. After an implant has osseointegrated, the abutment is screwed into the implant. It provides the foundation onto which the prosthetic tooth is attached.	The primary function is to connect the dental implant (which is anchored in the jawbone) to the prosthetic crown or bridge. After an implant has osseointegrated, the abutment is screwed into the implant. It provides the foundation onto which the prosthetic tooth is attached.	Substantial equivalent

X. Discussion of the Non-Clinical Testing:

Non-clinical testing data submitted (either in subject- or predicate submission) included:

- Engineering and dimensional analysis of original manufactures' components (abutments, implants & abutment screws) for determination of compatibility

- Fatigue testing per ISO 14801 according to FDA guidance for Industry and FDA Staff "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*" dated May 12, 2004.

- The digital dentistry workflow validation was completed on selected model of subject product lines with a digital dentistry workflow including a 3Shape scanner, 3Shape Abutment Designer Software (K155415) and CORiTEC Imes-Icore milling unit. The validations were provided for the subject abutment design library (not allowing the user to design outside the design limits set by Elos Medtech) to demonstrate use with the 3Shape Abutment Designer™ Software (K151455). The design library file (DME-file) provided by Elos Medtech includes design limits in accordance with *Electronic Package insert - Instruction For Use, Surgical & Prosthetic Guide – Customized Abutment* and *Electronic Package insert - Instruction For Use, Surgical & Prosthetic Guide – Hybrid Base*. The 3Shape Abutment Designer™ Software (K151455) prevents designing outside the specified design limits in the library file. Testing of design limits was conducted to show avoidance of designing outside the specified design limits.

- Biocompatibility testing for cytotoxicity according to ISO 10993-5. Cytotoxicity testing on identically manufactured abutments and prosthetic screws manufactured from the same material is leveraged from previously 510(k) cleared products (K230317/K231317). All tests showed the products to be non-cytotoxic.

- Sterilization validation according to ISO 17665-1 & ISO 17665-2, demonstrating a SAL of 10^{-6}. The sterilization and Dry-time studies can be leveraged from K230317/K231317 to the subject Elos Accurate® Customized Abutments and Elos Accurate Hybrid Base as material, size and geometry are substantial equivalent.

- To verify that a worst-case assembly made of Elos Medtech devices was MR conditional, a range of tests was performed on the worst-case assembly according to ASTM F2052, ASTM F2119, ASTM F2213 and ASTM F2182. The device has been assessed at 1.5 Tesla and 3 Tesla for displacement, torque, heating and image artifact in the MRI scanner, which proved that the proposed devices are MR conditional to use when having an MRI scan. The MR conditional safety evaluations are being leveraged from prior K230317/K231317 clearance. The MR tested item is made from the same material titanium TiAl6V4 ELI and having equivalent geometry as the proposed devices. The MR tested item is representative of the subject devices since it was a much more worst-case than the subject devices.

- To address the potential risk of damage to the implant-abutment connection geometry during the milling of the patient-matched portions of the Customized Abutment, validation testing of CAM restriction zones was conducted to show avoidance of damage or

modification of the connection geometry and locking of restriction zones from user editing in the CAM software.

XI. Conclusions:

Based on the test results and additional supporting documentation provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the previously listed predicate device.