



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

September 30, 2026

Re: K261327  
Trade/Device Name: Elos Accurate Hybrid Base  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: Class II  
Product Code: NHA, PNP  
Dated: August 27, 2026  
Received: August 27, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**ANDREW I. STEEN -S**

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

Enclosure

# Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261327

Please provide the device trade name(s).

Elos Accurate Hybrid Base

Please provide your Indications for Use below.

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]

Astra Tech EV 3.0 Ø3 Ø3

Astra Tech EV 3.6 Ø3.6 Ø3.6

Astra Tech EV 4.2 Ø4.2 Ø3.6 & Ø4.2

Astra Tech EV 4.8 Ø4.8 Ø4.2 & Ø4.8

Astra Tech EV 5.4 Ø5.4 Ø5.4

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 Bone Level NC Ø3.3 Ø3.3

Straumann Bone Level RC Ø4.1/Ø4.8 Ø4.1/Ø4.8

Straumann BLX RB/WB Ø3.4/Ø3.5/Ø4.5 Ø3.5/Ø3.75/Ø4/ Ø4.5/Ø5/Ø5.5/Ø6.5

Straumann TLX NT Ø3.5 Ø3.75/Ø4.5

Straumann TLX RT Ø4.8 Ø3.75/Ø4.5

Straumann TLX WT Ø6.5 Ø5.5/ Ø6.5

Neodent GM Ø3.5/Ø4.5/Ø5.5/Ø 6.5 Ø3.5/Ø3.75/Ø4/Ø4.3/Ø 5/Ø 6/Ø7

MegaGen AnyRidge Ø3.5/Ø4.0/Ø4.5/Ø5.0/Ø5.5 Ø4.0/Ø4.4/Ø4.9/Ø5.4/Ø5.9/Ø6.4/Ø6.9/Ø7.4/Ø7.9/Ø8.4

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

Astra Tech 3.0 Ø3 Ø3

Astra Tech 3.5/4.0 Ø3.5/Ø4 Ø3.5/Ø4

Astra Tech 4.5/5.0 Ø4.5/Ø5 Ø4.5/Ø5

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.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**510(k) Summary**  
**Elos Accurate® Hybrid Base™**  
**September 17, 2026**

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

**I. Submitting Company:** Elos Medtech Pinol A/S  
Engvej 33  
DK-3330 Goerloese  
Denmark

**Contact person:** Lise Terkelsen  
Regulatory Affairs Professional  
Tel: +45 21 60 55 60  
E-mail: [lise.terkelsen@elosmedtech.com](mailto:lise.terkelsen@elosmedtech.com)

**Second contact person:** Søren Rangstrup  
Product Development Manager  
E-mail: [soren.rangstrup@elosmedtech.com](mailto:soren.rangstrup@elosmedtech.com)

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

**III. Classification Name:** Endosseous Dental Implant Abutment

**IV. Classification:** Class II, 21 CFR 872.3630

**V. Product Code(s):** Primary: NHA  
Secondary: PNP

**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:**

- K242025 / SE 12/10/2024 - Elos Accurate® Hybrid Base™

**Reference Devices:**

- K120414 / SE 07/31/2012 – OSSEOSPEED PLUS
- K083550 / SE 02/26/2009 – STRAUMANN DENTAL IMPLANT SYSTEM
- K163194 / SE 07/14/2017 – Neodent Implant System - GM Line
- K180536 / SE 08/30/2018 – Neodent Implant System – GM Line
- K201225 / SE 09/04/2020 – Neodent Implant System - GM Helix Implants 7.0
- K173961 / SE 06/05/2018 – Straumann BLX Implant System

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- 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
- K091239 / SE 09/22/2009 – ASTRA TECH IMPLANT SYSTEM
- K122300 / SE 01/30/2013 – T3 DENTAL IMPLANT
- K013227 / SE 11/19/2001 – SCREW VENT IMPLANT; TAPERED SCREW VENT IMPLANT
- K200586 / SE 08/20/2020 – Straumann TLX Implant System
- K110955 / SE 11/22/2011 – ANYRIDGE INTERNAL IMPLANT SYSTEM
- K201860 / SE 02/19/2021 – Elos Accurate Hybrid Base
- K230317 / SE 09/01/2023 – Elos Accurate Hybrid Base
- K241722 / SE 09/13/2024 – Elos Accurate® Hybrid Base™; Elos Accurate® Customized Abutment

### VII. Product Description:

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™ functions as an interface between a dental implant and a zirconia superstructure. It attaches to the implant using the included prosthetic screw and connects to the zirconia superstructure through cementing. The Elos Accurate® Hybrid Base™ is a two-piece abutment composed of the Hybrid Base as the bottom-half and the zirconia superstructure as the top-half, which when assembled comprises the final finished medical device.

The Elos Accurate® Hybrid Base™ is available for two types: Engaging and Non-Engaging.

- The Hybrid Base™ Engaging which is intended for single tooth dental restorations and having an indexing feature, which avoid the Hybrid Base from rotating in the implant.
- The Hybrid Base™ Non-Engaging is intended for multiple tooth dental restorations and has no indexing feature, which allows the Hybrid Base to rotate in the implant.

The Elos Accurate® Hybrid Base™ is available with 4 different collar heights and is provided with a 7,5mm chimney which can be cut down to several heights by the user, to minimum 3,5 mm.

The Elos Accurate® Hybrid Base™ consists of a pre-manufactured prosthetic component in Titanium alloy per ASTM F136, as well as supporting digital library file for 510(k) cleared design software (3Shape Abutment Designer™ Software, K151455) which facilitates the design of a patient specific zirconia superstructure by the laboratory/clinician. The Elos Accurate® Hybrid Base™ fits directly to an endosseous dental implant. The laboratory designed superstructure is manufactured from 510(k) cleared Zirconia (Lava Plus, K011394) conforming to ISO 6872 - Type II, Class 5, according to digital dentistry workflow. For all Elos Accurate® Hybrid Base™ models the zirconia superstructure must be designed according to following limits:

## 510k summary

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

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

The laboratory designed superstructure is attached to the Elos Accurate® Hybrid Base by use of 510(k) cleared cement (Panavia V5, K150704) and the final prosthetic restoration is attached to the implant using a Prosthetic screw.

The Prosthetic Screw, also made of Titanium Alloy (ASTM F136), provided for the Elos Accurate® Hybrid Base™ is used to secure the final prosthetic restoration to the implant in the patient's mouth. The Prosthetic Screws have a hexalobular driver connection interface. The driver intended to be used with the Elos Accurate® Hexalobular Prosthetic Screws is the Elos Prosthetic Screwdriver 18mm, 26mm or 34mm (Ref. No. PS-AH18-1, PS-AH26-1, PS-AH34-1). These screwdrivers are Class I Exempt devices per FDA product code NDP.

The Elos Accurate® Hybrid Base has a gold anodized surface to increase the esthetics of the dental restoration - the same surface as in predicate device K242025.

The subject prosthetic screws provided are non-coated.

The Elos Accurate® Hybrid Base™ and the Prosthetic screw is delivered non-sterile, and the final restoration and corresponding screw is intended to be sterilized at the dental clinic before it is placed in the patient. The recommended sterilization procedure is full cycle pre-vacuum steam sterilization at a temperature of 132 °C (270°F) for 4 minutes. Dry time: 20 minutes.

The Elos Accurate® Hybrid Base™ is packed in 1 pc. packaging with the Elos Accurate® Hexalobular Prosthetic screw. The Screw is also available packed alone in 1 pcs packaging.

### VIII. Indications for Use:

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.

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|--------------------------------|------------------------|----------------------------|
| Astra Tech EV 3.0              | Ø3                     | Ø3                         |
| Astra Tech EV 3.6              | Ø3.6                   | Ø3.6                       |
| Astra Tech EV 4.2              | Ø4.2                   | Ø3.6 & Ø4.2                |
| Astra Tech EV 4.8              | Ø4.8                   | Ø4.2 & Ø4.8                |
| Astra Tech EV 5.4              | Ø5.4                   | Ø5.4                       |
| 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                         |

## 510k summary

|                         |                              |                                                       |
|-------------------------|------------------------------|-------------------------------------------------------|
| Straumann Bone Level NC | Ø3.3                         | Ø3.3                                                  |
| Straumann Bone Level RC | Ø4.1/Ø4.8                    | Ø4.1/Ø4.8                                             |
| Straumann BLX RB/WB     | Ø3.4/Ø3.5/Ø4.5               | Ø3.5/Ø3.75/Ø4/<br>Ø4.5/Ø5/Ø5.5/Ø6.5                   |
| Straumann TLX NT        | Ø3.5                         | Ø3.75/Ø4.5                                            |
| Straumann TLX RT        | Ø4.8                         | Ø3.75/Ø4.5                                            |
| Straumann TLX WT        | Ø6.5                         | Ø5.5/ Ø6.5                                            |
| Neodent GM              | Ø3.5/Ø4.5/Ø5.5/<br>Ø 6.5     | Ø3.5/Ø3.75/Ø4/<br>Ø4.3/Ø 5/Ø 6/Ø 7                    |
| MegaGen AnyRidge        | Ø3.5/Ø4.0/Ø4.5/<br>Ø5.0/Ø5.5 | Ø4.0/Ø4.4/Ø4.9/Ø5.4/Ø5.9/Ø6.4/Ø6<br>.9/Ø7.4/Ø7.9/Ø8.4 |
| 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                                                  |
| Astra Tech 3.0          | Ø3                           | Ø3                                                    |
| Astra Tech 3.5/4.0      | Ø3.5/Ø4                      | Ø3.5/Ø4                                               |
| Astra Tech 4.5/5.0      | Ø4.5/Ø5                      | Ø4.5/Ø5                                               |

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 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 devices.

Compared to the primary predicate device, the specific language (wording) of the Indications for Use Statements is equivalent except for implant system compatibility. The implant system compatibility of the subject device is extended to include compatibility with the Astra Tech EV, Biomet 3i Certain, Straumann Bone Level, Straumann BLX, Straumann TLX, Neodent GM, MegaGen AnyRidge, Zimmer Screw-vent, Astra Tech implant system platforms. The difference in implant system compatibility is substantiated by engineering and dimensional analysis of original manufacturers' components (abutments, implants & abutment screws) for determination of compatibility and new fatigue testing.

The approach of designing and manufacturing the zirconia superstructure 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 Predicate Device K242025). The subject device does not represent any new worst case, and is thereby covered by existing workflow validation, except the additional new digital libraries were validated as part of the subject submission, which included following:

## 510k summary

- Scanner: Intra oral scanner with accuracy  $>10\mu\text{m}$  (3shape Trios-series)
- 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)
- Superstructure Material: Zirconia conforming to ISO 6872 - Type II, Class 5 (3M Lava Plus Zirconia (K011394))
- Milling Unit: CORiTEC, imes-icore milling unit
- Adhesive material: Panavia V5 by KURARAY NORITAKE DENTAL (K150704)

| <b>Indications for Use</b><br><b>Subject Device</b><br><br><b>Elos Accurate® Hybrid Base™</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Indications for Use</b><br><b>Primary Predicate Device (K242025)</b><br><br><b>Elos Accurate® Hybrid Base™</b> | <b>Discussion</b>                                 |                            |                   |    |    |                   |      |      |                   |      |             |                   |      |             |                   |      |      |                   |      |       |                   |      |    |                   |    |    |                   |    |    |                |      |      |                |           |           |                     |                |                                 |                  |      |            |                  |      |            |               |      |           |            |                     |                             |                  |                          |                                                   |                   |      |           |                   |      |      |                   |      |      |                |    |    |                    |         |         |                    |         |         |                                                                                                  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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.</p> <p>The Elos Accurate® Hybrid Base™ is compatible with the implant systems listed in table 1:</p> <p><b>Table 1.</b></p> <table border="1"> <thead> <tr> <th>Implant Platform compatibility</th><th>Platform diameter [mm]</th><th>Implant Body diameter [mm]</th></tr> </thead> <tbody> <tr><td>Astra Tech EV 3.0</td><td>Ø3</td><td>Ø3</td></tr> <tr><td>Astra Tech EV 3.6</td><td>Ø3.6</td><td>Ø3.6</td></tr> <tr><td>Astra Tech EV 4.2</td><td>Ø4.2</td><td>Ø3.6 &amp; Ø4.2</td></tr> <tr><td>Astra Tech EV 4.8</td><td>Ø4.8</td><td>Ø4.2 &amp; Ø4.8</td></tr> <tr><td>Astra Tech EV 5.4</td><td>Ø5.4</td><td>Ø5.4</td></tr> <tr><td>Biomet 3i Certain</td><td>Ø3.4</td><td>Ø3.25</td></tr> <tr><td>Biomet 3i Certain</td><td>Ø4.1</td><td>Ø4</td></tr> <tr><td>Biomet 3i Certain</td><td>Ø5</td><td>Ø5</td></tr> <tr><td>Biomet 3i Certain</td><td>Ø6</td><td>Ø6</td></tr> <tr><td>Straumann Bone</td><td>Ø3.3</td><td>Ø3.3</td></tr> <tr><td>Straumann Bone</td><td>Ø4.1/Ø4.8</td><td>Ø4.1/Ø4.8</td></tr> <tr><td>Straumann BLX RB/WB</td><td>Ø3.4/Ø3.5/Ø4.5</td><td>Ø3.5/Ø3.75/Ø4/Ø4.5/Ø5/Ø5.5/Ø6.5</td></tr> <tr><td>Straumann TLX NT</td><td>Ø3.5</td><td>Ø3.75/Ø4.5</td></tr> <tr><td>Straumann TLX RT</td><td>Ø4.8</td><td>Ø3.75/Ø4.5</td></tr> <tr><td>Straumann TLX</td><td>Ø6.5</td><td>Ø5.5/Ø6.5</td></tr> <tr><td>Neodent GM</td><td>Ø3.5/Ø4.5/Ø5.5/Ø6.5</td><td>Ø3.5/Ø3.75/Ø4/Ø4.3/Ø5/Ø6/Ø7</td></tr> <tr><td>MegaGen AnyRidge</td><td>Ø3.5/Ø4.0/Ø4.5/Ø5.0/Ø5.5</td><td>Ø4.0/Ø4.4/Ø4.9/Ø5.4/Ø5.9/Ø6.4/Ø6.9/Ø7.4/Ø7.9/Ø8.4</td></tr> <tr><td>Zimmer Screw-vent</td><td>Ø3.5</td><td>Ø3.7/Ø4.1</td></tr> <tr><td>Zimmer Screw-vent</td><td>Ø4.5</td><td>Ø4.7</td></tr> <tr><td>Zimmer Screw-vent</td><td>Ø5.7</td><td>Ø6.0</td></tr> <tr><td>Astra Tech 3.0</td><td>Ø3</td><td>Ø3</td></tr> <tr><td>Astra Tech 3.5/4.0</td><td>Ø3.5/Ø4</td><td>Ø3.5/Ø4</td></tr> <tr><td>Astra Tech 4.5/5.0</td><td>Ø4.5/Ø5</td><td>Ø4.5/Ø5</td></tr> </tbody> </table> <p>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.</p> | Implant Platform compatibility                                                                                    | Platform diameter [mm]                            | Implant Body diameter [mm] | Astra Tech EV 3.0 | Ø3 | Ø3 | Astra Tech EV 3.6 | Ø3.6 | Ø3.6 | Astra Tech EV 4.2 | Ø4.2 | Ø3.6 & Ø4.2 | Astra Tech EV 4.8 | Ø4.8 | Ø4.2 & Ø4.8 | Astra Tech EV 5.4 | Ø5.4 | Ø5.4 | Biomet 3i Certain | Ø3.4 | Ø3.25 | Biomet 3i Certain | Ø4.1 | Ø4 | Biomet 3i Certain | Ø5 | Ø5 | Biomet 3i Certain | Ø6 | Ø6 | Straumann Bone | Ø3.3 | Ø3.3 | Straumann Bone | Ø4.1/Ø4.8 | Ø4.1/Ø4.8 | Straumann BLX RB/WB | Ø3.4/Ø3.5/Ø4.5 | Ø3.5/Ø3.75/Ø4/Ø4.5/Ø5/Ø5.5/Ø6.5 | Straumann TLX NT | Ø3.5 | Ø3.75/Ø4.5 | Straumann TLX RT | Ø4.8 | Ø3.75/Ø4.5 | Straumann TLX | Ø6.5 | Ø5.5/Ø6.5 | Neodent GM | Ø3.5/Ø4.5/Ø5.5/Ø6.5 | Ø3.5/Ø3.75/Ø4/Ø4.3/Ø5/Ø6/Ø7 | MegaGen AnyRidge | Ø3.5/Ø4.0/Ø4.5/Ø5.0/Ø5.5 | Ø4.0/Ø4.4/Ø4.9/Ø5.4/Ø5.9/Ø6.4/Ø6.9/Ø7.4/Ø7.9/Ø8.4 | Zimmer Screw-vent | Ø3.5 | Ø3.7/Ø4.1 | Zimmer Screw-vent | Ø4.5 | Ø4.7 | Zimmer Screw-vent | Ø5.7 | Ø6.0 | Astra Tech 3.0 | Ø3 | Ø3 | Astra Tech 3.5/4.0 | Ø3.5/Ø4 | Ø3.5/Ø4 | Astra Tech 4.5/5.0 | Ø4.5/Ø5 | Ø4.5/Ø5 | <p>The Elos Accurate® Hybrid Base™ is intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. 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| Implant Platform compatibility                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         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| Astra Tech EV 3.6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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| Astra Tech EV 4.2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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| Astra Tech EV 4.8                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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| Astra Tech EV 5.4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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| Straumann BLX RB/WB                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    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| Straumann TLX NT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       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| Straumann TLX RT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       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| Straumann TLX                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          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| Zimmer Screw-vent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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| Zimmer Screw-vent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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| Zimmer Screw-vent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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| Astra Tech 3.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         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| Astra Tech 3.5/4.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     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| Astra Tech 4.5/5.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     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| Implant Platform compatibility                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Platform diameter [mm]                                                                                            | Implant Body diameter [mm]                        |                            |                   |    |    |                   |      |      |                   |      |             |                   |      |             |                   |      |      |                   |      |       |                   |      |    |                   |    |    |                   |    |    |                |      |      |                |           |           |                     |                |                                 |                  |      |            |                  |      |            |               |      |           |            |                     |                             |                  |                          |                                                   |                   |      |           |                   |      |      |                   |      |      |                |    |    |                    |         |         |                    |         |         |                                                                                                  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| Astra Tech EV 3.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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| Astra Tech EV 3.6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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| Astra Tech EV 4.2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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| Astra Tech EV 4.8                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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| Astra Tech EV 5.4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      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## 510k summary

| Element of Comparison                   | Subject Device<br><br>Elos Accurate® Hybrid Base™<br>Elos Medtech Pinol A/S               | Primary Predicate Device K242025<br>Elos Accurate® Hybrid Base™<br>Elos Medtech Pinol A/S | Discussion                                                                                                                                                                                                                                   |
|-----------------------------------------|-------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Intended Use                            | 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                            | N/A                                                                                                                                                                                                                                          |
| Abutment Designs                        | 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<br>Superstructure cement-retained                      | Abutment screw-retained to implant<br>Superstructure cement-retained                      | Substantial equivalent                                                                                                                                                                                                                       |
| Restoration                             | Single-unit<br>Multi-unit                                                                 | Single-unit<br>Multi-unit                                                                 | Substantial equivalent                                                                                                                                                                                                                       |
| Abutment/Implant Platform Diameter (mm) | Ø3.0 – Ø6.5 [mm]                                                                          | Ø3.0 – Ø5.4 [mm]                                                                          | Abutment/Implant platform diameter for the subject device is up to 6.5 mm, which is larger than the primary predicate device. The larger diameter does not represent a new worst case scenario and thereby affect the safety of the product. |
| Abutment Angle                          | 20° maximum                                                                               | 20° maximum                                                                               | Substantial equivalent                                                                                                                                                                                                                       |
| <b>Materials</b>                        |                                                                                           |                                                                                           |                                                                                                                                                                                                                                              |
| -Abutment titanium component            | Ti-6Al-4V alloy                                                                           | Ti-6Al-4V alloy                                                                           | Substantial equivalent                                                                                                                                                                                                                       |
| - Screw                                 | Ti-6Al-4V alloy                                                                           | Ti-6Al-4V alloy                                                                           | Substantial equivalent                                                                                                                                                                                                                       |
| - Superstructure                        | Zirconia conforming to ISO 6872 - Type II, Class 5                                        | Zirconia conforming to ISO 6872 - Type II, Class 5                                        | Substantial equivalent                                                                                                                                                                                                                       |
| Surface                                 | Abutment: Anodized<br>Screw: Non-coated,                                                  | Abutment: Anodized<br>Screw: Anodized                                                     | The surface of the Subject Abutment is Substantial equivalent to Primary Predicate Device K242025.<br><br>The subject screw is provided Non-coated equal to OEM screws provided by OEM implant manufacturers.                                |
| Design Workflow                         | 3Shape intra oral scanner Trios (3Shape A/S),                                             | 3Shape intra oral scanner Trios (3Shape A/S),                                             | Substantial equivalent                                                                                                                                                                                                                       |

## 510k summary

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|-------------------------------|----------------------------------------------------------|----------------------------------------------------------|------------------------|
|                               | 3Shape Abutment Designer Software (3Shape A/S) - K151455 | 3Shape Abutment Designer Software (3Shape A/S) - K151455 |                        |
| <b>Manufacturing Workflow</b> | CORiTEC milling unit (Imes-Icore)                        | CORiTEC milling unit (imes-icore)                        | Substantial equivalent |

The data included in this submission demonstrates substantial equivalence to the predicate device listed above.

Overall, the subject device has the following substantial equivalencies to the predicate device:

- has the same intended use,
- uses the same operating principle,
- incorporates similar basic design,
- incorporates the same or very similar materials, and
- is to be sterilized prior to use, using the same processes.

### **X. Discussion of the Non-Clinical Testing:**

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

- Performance testing, ie. fatigue testing, has been performed on the Hybrid Base and Prosthetic Screw subject devices. The fatigue testing met ISO 14801 requirements 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 and demonstrated comparable mechanical performance to the predicate device with no new worst case conditions.
- Engineering and dimensional analysis of original manufacturers’ components (abutments, implants & abutment screws) was performed on the subject devices for determination of compatibility.
- The digital dentistry workflow validation was completed on selected models of subject product line with a digital dentistry workflow including a 3Shape scanner, 3Shape Abutment Designer Software (K155415) and CORiTEC Imes-Icore milling unit. The validation was provided for the predicate K242025 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 included design limits in accordance with Electronic Package insert - Instruction For Use, Surgical & Prosthetic Guide. The 3Shape Abutment Designer™ Software (K151455) prevents designing outside the specified design limits in the library file. Since the subject device uses identical design and manufacturing workflow (as for the Primary Predicate Device K242025), including identical design limits built in the design library file (DME-file), the subject device does not represent any new worst case, than the worst case documented in K242025. Hence the new variants are thereby covered by existing workflow validation submitted in K242025.
- A design limitation test is performed with the purpose of demonstrating in 3Shape Dental System design software, that the user cannot design the zirconia superstructure for Elos

## 510k summary

Accurate Hybrid base outside the limitations built in the digital libraries relevant for this submission, provided by Elos Medtech.

- Sterilization validation according to ISO 17665-1 & ISO 17665-2, demonstrating a SAL of  $10^{-6}$  is leveraged from predicate device.
- The Hybrid Base™ and Prosthetic Screws are titanium alloy (ASTM F136) with a long clinical history of safe use in dental abutments. Consistent with FDA's ISO 10993-1 approach for well-characterized materials with long histories of safe use, confirmatory cytotoxicity testing was performed on final-finished devices and leveraged from prior clearance (K242025). The nature and duration of contact are permanent tissue/bone contact (>30 days) for the abutment; the screw has no direct patient contact (internal to the restoration). Tests showed the products to be non-cytotoxic.
- MR Conditional labeling testing is being leveraged from predicate devices in K242025 and the subject devices do not present a new worst-case for the leveraged testing.

### **XI. Conclusion:**

The Elos Accurate® Hybrid Base™ (with Elos Prosthetic Screws) is substantially equivalent to the primary predicate device (K242025). It has the same intended use and fundamental technological characteristics, and the submitted performance data support that any differences do not raise new questions of safety or effectiveness.