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

October 16, 2025

Re: K251497
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: May 15, 2025
Received: September 19, 2025

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

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.	K251497

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]
Nuventus NV.C NP, Ø3,5, Ø3,5 / Ø4,3
Nuventus NV.C RP, Ø5.0, Ø5.0

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™
October 14, 2025

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

Contacts: Lise Terkelsen
Regulatory Affairs Professional
Tel: +45 21 60 55 60
E-mail: lise.terkelsen@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:
- K233081 / SE 11/15/2024 – NUVENTUS NV.C™ Dental Implant System
- K201860 / SE 02/19/2021 – Elos Accurate® Hybrid Base™

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) according to digital dentistry workflow. For all Elos Accurate® Hybrid Base™ models the zirconia superstructure must be designed according to following limits:

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.

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. 042.0018, 042.0026 or 042.0034). 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 are provided are either non-coated or surface coated with DLC (identical to the DLC coating in reference device K201860).

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.
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]
Nuventus NV.C NP	Ø3,5	Ø3,5 / Ø4,3
Nuventus NV.C RP	Ø5.0	Ø5.0

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 Nuventus NV.C implant system platforms. 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 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:

- 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)
- Zirconia Material: 3M Lava Plus Zirconia (K011394)
- Milling Unit: CORiTEC, imes-icore milling unit
- Adhesive material: Panavia V5 by KURARAY NORITAKE DENTAL (K150704)

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Indications for Use
Subject Device

Elos Accurate® Hybrid Base™

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Indications for Use
Primary Predicate Device (K242025)

Elos Accurate® Hybrid Base™

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Discussion

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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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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

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.

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The Indication for use for the subject device is similar to the Primary Predicate Device (K242025) beside compatibility table 1. which have been replaced by a new implant system (Nuventus implant system).

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 (provided with this subject 510(k)).

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Element of Comparison	Subject Device Elos Accurate® Hybrid Base™ Elos Medtech Pinol A/S	Primary Predicate Device K242025 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	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 Superstructure cement-retained	Abutment screw-retained to implant Superstructure cement-retained	Substantial equivalent
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Substantial equivalent
Abutment/Implant Platform Diameter (mm)	Ø3.5 – Ø5.0 [mm]	Ø3.0 – Ø5.4 [mm]	Implant diameters for the subject device are within range of the Primary Predicate Device K242025.
Abutment Angle	20° maximum	20° maximum	Substantial equivalent
Materials			
-Abutment titanium component	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Substantial equivalent
- Screw	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Substantial equivalent
-Zirconia superstructure	3M Lava zirconia	3M Lava zirconia	Substantial equivalent
Surface	Abutment: Anodized Screw: Non-coated, DLC coated	Abutment: Anodized Screw: Anodized	The surface of the Subject Abutment is Substantial equivalent to Primary Predicate Device K242025. The subject screw is provided Non-coated or DLC coated identical to reference device K201860.
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	Substantial equivalent
Manufacturing Workflow	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:
  - Nuventus NV.C NP, the Prosthetic Screw M1.6 NV.C NP and Nuventus implant – NV.C NP, Ø3,5x13 mm.
  - Nuventus NV.C NP, the Prosthetic Screw M1.6 NV.C NP and Nuventus implant – NV.C NP, Ø4,3x13 mm

  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 mechanical performance comparable to the predicate device.

- Engineering and dimensional analysis of original manufactures' components (abutments, implants & abutment screws) was performed on the subject devices for determination of compatibility.

- Sterilization validation according to ISO 17665-1 & ISO 17665-2, demonstrating a SAL of 10^{-6} is leveraged from predicate device.

- The subject device uses identical design and manufacturing workflow (3Shape scanner, 3Shape Abutment Designer Software (K155415) and CORiTEC Imes-Icore milling unit) as for the Primary Predicate Device K242025, including identical design limits built in the subject design library file (DME-file), the subject device does not represent any new worst case, than the worst case documented in K242025.
  The design library file (DME-file), intended for Nuventus NV.C (NP, RP) models, provided by Elos Medtech includes 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.
  A validation of the new digital libraries has been performed. This library validation (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 Accurate Hybrid base outside the limitations built in the digital libraries relevant for this submission, provided by Elos Medtech.

- Biocompatibility was evaluated according to ISO 10993-1 and the FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1:

Evaluation and testing within a risk management process" issued September 8, 2023. Based on this guidance and the common usage of the employed materials demonstrating biocompatibility via cytotoxicity testing was found sufficient. A cytotoxicity test according to ISO 10993-5 of a complete restoration produced via the described validated workflow was performed. Cytotoxicity testing on identically manufactured hybrid bases and prosthetic screws along with zirconia superstructures manufactured from the same material is leveraged from previously 510(k) cleared products. All 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:

Based on the comprehensive testing and analysis presented, the subject devices have been shown to be substantially equivalent to the predicate devices in terms of safety, performance, and intended use.