Elos Medtech Pinol A/S
Ana Paula Holtz
Regulatory Affairs Professional
Engvej 33
Goerloese, 3330
DENMARK

May 20, 2026

Re: K253774
Trade/Device Name: Elos Accurate® Denture Fixation System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 21, 2026
Received: April 20, 2026

Dear Ana Paula Holtz:

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 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) 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.*

510(k) Number *(if known)*
K253774

Device Name
Elos Accurate® Denture Fixation System

Indications for Use *(Describe)*
The Elos Accurate® Denture Fixation System is intended to retain removable overdentures for patients with partial or complete edentulism.

Implant Platform compatibility Platform diameter [mm] Implant diameter [mm]
Astra Tech EV 3.6 Platform diameter [mm]Ø2.9 Implant diameter [mm] Ø3.6
Astra Tech EV 4.2 Platform diameter [mm]Ø3.5 Implant diameter [mm] Ø4.2
Astra Tech EV 4.8 Platform diameter [mm]Ø4.1 Implant diameter [mm] Ø4.8
Astra Tech EV 5.4 Platform diameter [mm]Ø4.6 Implant diameter [mm] Ø5.4
Straumann BLX RB/WB Platform diameter [mm]Ø2.9 Implant diameter [mm] Ø3.5/ Ø3.75/ Ø4/ Ø4.5/ Ø5/ Ø5.5/ Ø6.5
Nobel CC NP Platform diameter [mm]Ø3.0 Implant diameter [mm] Ø3.5/ Ø3.75
Nobel CC RP Platform diameter [mm]Ø3.4 Implant diameter [mm] Ø4.3/ Ø5
Nobel CC WP Platform diameter [mm]Ø4.4 Implant diameter [mm] Ø5.5/ Ø6
Neodent GM Platform diameter [mm]Ø3 Implant diameter [mm] Ø3.5/ Ø3.75/Ø4/Ø4.3/Ø5/Ø6/Ø7
Zimmer Screw-vent 3.5 Platform diameter [mm]Ø3.4 Implant diameter [mm] Ø3.7/Ø4.1
Zimmer Screw-vent 4.5 Platform diameter [mm]Ø4.4 Implant diameter [mm] Ø4.7
Zimmer Screw-vent 5.7 Platform diameter [mm]Ø5.6 Implant diameter [mm] Ø6.0

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary
# K253774
# Elos Accurate® Denture Fixation System
# May 20, 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

**Contacts:** Ana Paula Holtz
Regulatory Affairs Professional
Tel: +45 48216400
E-mail: ana.holtz@elosmedtech.com


**II. Proprietary Trade Name:** Elos Accurate® Denture Fixation System

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

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

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

**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:**
- K200827 / SE 09/02/2020 – LOCATOR R-Tx

**Reference Devices:**
- K120414 / SE 07/31/2012 – OSSEOSPEED PLUS
- K133731 / SE 05/08/2014 – NOBELACTIVE WIDE PLATFORM (WP)
- K071370 / SE 08/03/2007 – NOBELACTIVE INTERNAL CONNECTION IMPLANT
- K181703 / SE 12/28/2018 – Straumann BLX Line Extension - Implants, SRAs and Anatomic Abutment
- K173961 / SE 06/05/2018 – Straumann BLX Implant System
- K191256 / SE 12/27/2019 – Straumann BLX Ø3.5 mm Implants
- K212533 / SE 01/28/2022 – BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants

- K210855 / SE 06/21/2021 – Straumann BLX 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
- K013227 / SE 11/19/2001 – SCREW VENT IMPLANT ; TAPERED SCREW VENT IMPLANT

**VII. Product Description:**

The Elos Accurate® Denture Fixation System consists of a denture abutment, manufactured from Titanium Alloy Ti-6AI-4V ELI with titanium carbonitride coating (TiCN), coupled with a denture cap, manufactured from Titanium Alloy Ti-6AI-4V ELI, through a flexible retaining ring, manufactured from Polyamide 12, to facilitate a snapping system. The denture abutment is fixated to the dental implant through a thread connection. The denture abutment is available at different gingival heights (1 to 6 mm) and is compatible with different implant systems. All components are single-use and are delivered non-sterile and are intended to be cleaned and sterilized/disinfected prior to use in the patient.

The Elos Accurate® Denture Fixation System for endosseous dental implants is designed for use with overdentures or partial dentures that are retained, either fully or partially, by endosseous implants in the mandible or maxilla. The Elos Accurate® Denture Fixation System allows for the dentures to be removed and attached by the patient. The Elos Accurate® Denture Fixation System is intended to be used by dental patients with edentulism.

The Elos Accurate® Denture Fixation System is designed to accommodate a path of insertion on implants that are divergent up to 30°. Elos Accurate® Denture Fixation System must only be used on implants angled up to 20° relative to the occlusal load. An implant retained denture comprises the use of 2-6 pcs. of dental implants.

**VIII. Indications for Use:**

The Elos Accurate® Denture Fixation System is intended to retain removable overdentures for patients with partial or complete edentulism.

The Elos Accurate® Denture Fixation System is compatible with the implant systems listed in table 1:

| **Implant Platform compatibility** | **Platform diameter [mm]** | **Implant diameter [mm]** |
|---|---|---|
| Astra Tech EV 3.6 | Ø2.9 | Ø3.6 |
| Astra Tech EV 4.2 | Ø3.5 | Ø4.2 |
| Astra Tech EV 4.8 | Ø4.1 | Ø4.8 |
| Astra Tech EV 5.4 | Ø4.6 | Ø5.4 |
| Straumann BLX RB/WB | Ø2.9 | Ø3.5/Ø3.75/Ø4/ Ø4.5/Ø5/Ø5.5/Ø6.5 |
| Nobel CC NP | Ø3.0 | Ø3.5/Ø3.75 |
| Nobel CC RP | Ø3.4 | Ø4.3/Ø5 |
| Nobel CC WP | Ø4.4 | Ø5.5/ Ø6 |
| Neodent GM | Ø3 | Ø3.5/ Ø3.75/Ø4/Ø4.3/Ø5/Ø6/Ø7 |

| | | |
|---|---|---|
| Zimmer Screw-vent 3.5 | Ø3.4 | Ø3.7/Ø4.1 |
| Zimmer Screw-vent 4.5 | Ø4.4 | Ø4.7 |
| Zimmer Screw-vent 5.7 | Ø5.6 | Ø6.0 |

Table 1: compatible implant systems

**IX. Summary of Technological Characteristics**:

The Elos Accurate® Denture Fixation System for endosseous dental implants is designed for use with overdentures or partial dentures that are retained, either fully or partially, by endosseous implants in the mandible or maxilla.

| **Indications for Use**<br>**Subject Device**<br>Elos Accurate® Denture Fixation System | **Indications for Use**<br>**Primary Predicate Device (K200827)**<br>LOCATOR R-Tx | **Discussion** |
|---|---|---|
| The Elos Accurate® Denture Fixation System is intended to retain removable overdentures for patients with partial or complete edentulism. | The LOCATOR R-Tx® Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla. | The Indication for use for the Subject Device is similar to the Primary Predicate Device (K200827). |

| Element of Comparison | Subject Device<br><br>Elos Accurate® Denture Fixation System | Primary Predicate Device (K200827)<br>LOCATOR R-Tx | Discussion |
|---|---|---|---|
| **Mode of Operation** | Abutment design that connects to a housing embedded in a denture ridge, which nylon retaining rings are used to allow connection and disconnection of the denture to the abutment for "removable" denture solution for the patient. | Abutment design that connects to a housing embedded in a denture ridge, which nylon inserts are used to allow connection and disconnection of the denture to the abutment for "removable" denture solution for the patient. | Equivalent |
| **Prothesis attachment** | Overdenture attachment | Overdenture attachment | Equivalent |
| **Restoration** | Overdenture | Overdenture | Equivalent |
| **Abutment Platform Diameter (mm)** | 2.9 – 5.6 | 2.75 - 6.0 | Similar |
| **Implant divergence allowance** | 30° | 30° | Equivalent |
| **Abutment angle** | Straight | Straight | Equivalent |
| **Retention type to implant body** | Screw | Screw | Equivalent |
| **Material** | | | |
| **Abutment** | Titanium 6Al-4V ELI | Titanium 6Al-4V ELI | Equivalent |
| **Abutment coating** | Titanium Carbon Nitride (TiCN) | Titanium Carbon Nitride (TiCN) or Titanium Nitride (TiN) | Equivalent |
| **Prosthetic Retention Component** | Polyamide 12 (Nylon) | Nylon or PEEK | Equivalent |
| **Denture component** | Titanium 6Al-4V ELI Anodized | Titanium-6Al-4V Anodized | Equivalent |
| **Abutment Height** | 1, 2, 3, 4, 5 and 6 mm | 1, 2, 3, 4, 5 and 6 mm | Equivalent |
| **Construction** | Three pieces | Three pieces | Equivalent |
| **Components** | Abutment, retaining ring, denture cap | Abutment, retention insert, denture cap | Equivalent |
| **Implant to Abutment Connection** | Different implant platforms | Different implant platforms | Equivalent |
| **Abutment to restoration connection** | Snap on feature | Snap on feature | 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 similar intended use,
- uses similar operating principle,
- incorporates similar basic design,
- incorporates 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 included:

- Modified surface (i.e., BALIMED TICANA and anodized surface) was characterized as per recommendation of the FDA guidance for Industry and FDA Staff "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments.*" Morphological examination was performed using Scanning Electron Microscopy (SEM) analysis and Roughness Testing. Mechanical integrity of the modified surfaces was assessed through a Hardness Test, Scratch Test, shear test as per ASTM F1044, Tensile test as per ASTM F1147.
- Performance testing, ie. fatigue testing, has been performed on the Elos Accurate Denture Fixation System 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 mechanical performance comparable to the predicate device.
- Dimensional analysis and reverse engineering of the implant-to-abutment connection platform were performed, using the OEM implant body, OEM abutment, OEM screw. The reverse engineering included an assessment of maximum and minimum dimensions of critical design aspects and tolerances of the OEM implant body, OEM abutment, OEM abutment screw, along with cross-sectional images of the submission device and compatible implant body. The testing demonstrated implant to abutment compatibility and has established substantial equivalency of the proposed device with reference devices.
- The cleaning and sterilization validation is based on ISO 17665-1, ISO 17664, AAMI ST79, and AAMI TIR12, demonstrating a SAL of $10^{-6}$ for comparable Ti-6Al-4V components.
- Biocompatibility testing was conducted based upon ISO 10993-1 (2018): Biological evaluation of medical devices – Part 1: "Evaluation and testing within a risk management process" and FDA guidance for Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" – Guidance for Industry and Food and Drug Administration Staff - September 2023. Cytotoxicity, sensitization, and irritation testing were conducted according to ISO 10993-5, 10993-10, and 10993-23 respectively.
- MRI safety was evaluated by MED Institute and McGowan Associates using ASTM F2052, F2213, F2119, F2182, ASTM F2503, and FDA's 2023 MRI guidance, confirming that the

Denture Fixation abutments are MR Conditional and do not present a new worst-case relative to the previously tested devices.

**XI. Conclusion:**

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