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

November 30, 2022

Re: K222044
Trade/Device Name: Elos Accurate® Customized Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA, PNP

Dear Lise Terkelsen:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter issued on November 30, 2022. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Andrew Steen, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6284, Andrew.Steen@fda.hhs.gov.

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

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

Re: K222044
Trade/Device Name: Elos Accurate® Customized Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: October 28, 2022
Received: October 31, 2022

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

Sincerely,

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

510(k) Number: K222044
Device Name: Elos Accurate® Customized Abutment

Indications for Use

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

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Nobel Replace NP	3.5	3.5
Nobel Replace RP	4.3	4.3
Nobel Replace WP	5	5
Nobel Replace 6.0	6	6
Nobel CC 3.0	3	3
Nobel CC NP	3.5	3.5 & 3.75
Nobel CC RP	3.9	4.3 & 5
Nobel CC WP	5.1	5.5
Straumann Bone Level NC	3.3	3.3
Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8
Astra Tech 3.5/4.0	3.5 & 4	3.5 & 4
Astra Tech 4.5/5.0	4.5 & 5	4.5 & 5
Astra Tech EV 3.6	3.6	3.6
Astra Tech EV 4.2	4.2	3.6 & 4.2
Astra Tech EV 4.8	4.8	4.2 & 4.8
Astra Tech EV 5.4	5.4	5.4
Brånemark NP	3.5	3.3
Brånemark RP	4.1	3.75, 4 & 5
Brånemark WP	5.1	5 & 6

All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

Prescription Use__X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
Elos Accurate® Customized Abutment
November 30, 2022

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

I. Company:

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

Contacts:

Lise Terkelsen
Regulatory Affairs Specialist
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E-mail: lise.terkelsen@elosmedtech.com

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

II. Proprietary Trade Name: Elos Accurate® Customized Abutment

III. Classification Name: Endosseous Dental Implant Abutment

IV. Classification: Class II, 21 CFR 872.3630

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

VI. Identification of Legally Marketed Devices:
The design features, materials and Indications for Use of the subject devices are substantially equivalent to the predicate devices noted below.

Primary Predicate Device:
- K190299 / SE 06/26/2019 – Elos Accurate® Customized Abutment
- K171799 / SE 01/15/2018 - Elos Accurate® Customized Abutment
- K192457 / SE 01/02/2020 - Elos Accurate® Customized Abutment
- K191890 / SE 02/06/2020 - Elos Accurate® Customized Abutment

Reference Devices:
- K201860 / SE 02/19/2021 - Elos Accurate® Hybrid Base
- K151455 / SE 06/09/2016 - 3Shape Abutment Designer Software

VII. Product Description:

The Elos Accurate® Customized Abutment is a patient specific abutment intended for attaching to dental implants in order to provide basis for single- or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to the implant using the included Elos Prosthetic Screw and attached to the crown/coping manually by cementation. The Elos Accurate® Customized Abutment consists of an Abutment Blank used in fabricating of a full patient-specific abutment in Titanium alloy per ASTM F136. The Abutment Blank used in creation of the Elos Accurate® Customized Abutment has a pre-manufactured connection interface that fits directly to a pre-specified dental implant. The customized shape of the abutment is intended to be manufactured according to a digital dentistry workflow. The Elos Accurate® Customized Abutment is delivered non-sterile and the final restoration including corresponding Elos Prosthetic Screw is intended to be sterilized at the dental clinic before it is placed in the patient. The Elos Accurate® Customized Abutment provides clinicians and laboratories with a prosthetic device that can be used in definitive (permanent) single- or multi restorations.

The Elos Accurate library file has built-in design limitations, and the user isn't allowed to exceed these limitations. The material thickness should not be less than 0.4 or 0.5 mm depend on implant platform compatibility (see Table A). The gingival height should not be less than 0.5mm or exceed 5 mm. The maximum angulation should not exceed 30° or 20° depend on implant platform compatibility (see Table A). The post height should not be less than 4 mm.

Table A.

Implant Platform compatibility	Platform diameter [mm]	Max angulation	Min wall thickness
Nobel Replace NP	3.5	30°	0,4 mm
Nobel Replace RP	4.3	30°	0,4 mm
Nobel Replace WP	5	30°	0,4 mm
Nobel Replace 6.0	6	30°	0,4 mm
Nobel CC 3.0	3	30°	0,4 mm
Nobel CC NP	3.5	30°	0,4 mm
Nobel CC RP	3.9	30°	0,4 mm
Nobel CC WP	5.1	30°	0,4 mm
Straumann Bone Level NC	3.3	30°	0,4 mm
Straumann Bone Level RC	4.1 & 4.8	30°	0,4 mm
Astra Tech 3.5/4.0	3.5 & 4	30°	0,4 mm
Astra Tech 4.5/5.0	4.5 & 5	30°	0,4 mm
Astra Tech EV 3.6	3.6	30°	0,4 mm
Astra Tech EV 4.2	4.2	30°	0,4 mm
Astra Tech EV 4.8	4.8	30°	0,4 mm
Astra Tech EV 5.4	5.4	30°	0,4 mm
Brånemark NP	3.5	20°	0,5 mm
Brånemark RP	4.1	20°	0,5 mm
Brånemark WP	5.1	20°	0,5 mm

VIII. Indications for Use:

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

Table 1.

Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Nobel Replace NP	3.5	3.5
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Nobel CC RP	3.9	4.3 & 5
Nobel CC WP	5.1	5.5
Straumann Bone Level NC	3.3	3.3
Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8
Astra Tech 3.5/4.0	3.5 & 4	3.5 & 4
Astra Tech 4.5/5.0	4.5 & 5	4.5 & 5
Astra Tech EV 3.6	3.6	3.6
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Brånemark NP	3.5	3.3
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Brånemark WP	5.1	5 & 6

All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

IX. Summary of the Technological Characteristics:

The subject devices have similar Indications for Use, intended use, designs, sizes and configurations, materials, and principles of operation as the primary predicate device Elos Accurate® Customized Abutment Device (K190299, K171799, K192457, K191890). In order to determine nominal dimensions and tolerances of the Elos Accurate® Customized Abutment products, measuring- and dimensional analyses of original manufacturers' components (abutments, implants & abutment screws) have been made.

Comparing to the primary predicate device, the specific language (wording) of the Indications for Use Statements is identical except for the change in manufacturing from an FDA registered Elos Medtech approved milling facility to that the abutments should be designed and manufactured using a specific digital dentistry workflow.

The clamping of the Subject device during milling is changed to the opposite end than the connection interface which differ from Primary Predicate Device (K190299, K171799, K192457, K191890). This difference has no impact on the final customized abutment design.

<table>
<tr><th>Element of Comparison</th><th>Indications for Use</th></tr>
<tr><td>Subject Device

Elos Accurate® Customized Abutment</td><td>The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.
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<tr><td>Primary Predicate Devices (K190299 171799, 192457, 191890)
Elos Accurate® Customized Abutment</td><td>The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.
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Nobel CC 3.0	3	3
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Brånemark NP	3.5	3.3
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Brånemark WP	5.1	5 & 6

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

Element of Comparison	Subject Device **Elos Accurate® Customized Abutment** Elos Medtech Pinol A/S	Primary Predicate Device K190299, K192457, K171799, K191890 **Elos Accurate® Customized Abutment** Elos Medtech Pinol A/S	Reference device K201860 **Elos Accurate® Hybrid Base** Elos Medtech Pinol A/S
Intended Use	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function
Reason for Predicate/Reference	Not applicable	Abutment Design Engineering and dimensional analysis	Digital dentistry workflow
Abutment Designs	Customized abutment mounted on the implant fixed with a screw	Customized abutment mounted on the implant fixed with a screw	2 piece – zirconia bonded to hybrid base mounted on to the implant and fixed with a screw
Prosthesis Attachment	Abutment screw-retained to implant	Abutment screw-retained to implant	Abutment screw-retained to implant Superstructure cement-retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Abutment/Implant Platform Diameter (mm)	3.0 – 6.0	3.0 – 6.0	3.0 – 6.0
Abutment Angle	Up to 30° maximum	Up to 30° maximum	20° maximum
Materials			
Abutment	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy
Screw	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy
Surface	Non-coated, Medicarb coating on screw	Non-coated, Medicarb coating on screw	Non-coated, Medicarb coating on screw
Design Workflow	3Shape scanner (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455	Elos Medtech approved milling facility.	3Shape scanner (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455
Manufacturing Workflow	CORiTEC milling unit (imes-icore)	Elos Medtech approved milling facility.	CORiTEC milling unit (imes-icore)

The data included in this submission demonstrate substantial equivalence to the predicate device and/or reference 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 the same basic design,
- incorporates the same or very similar materials, and
- is to be sterilized using the same processes.

X. Discussion of the Non-Clinical Testing:

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

- Engineering and dimensional analysis of original manufactures' components (abutments, implants & abutment screws) for determination of compatibility. (The compatibility analysis is conducted on primary predicate device (K190299, K171799, K192457, K191890) and can be leveraged to the subject Elos Accurate Customized Abutments as material, size and geometry are substantial equivalent)
- Fatigue testing per ISO 14801 according to FDA guidance for Industry and FDA Staff "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*" dated May 12, 2004. The Fatigue test are conducted on the primary predicate device (K190299, K171799, K192457, K191890) and can be leveraged to the subject Elos Accurate Customized Abutments as material, size and geometry are substantial equivalent
- Biocompatibility testing for cytotoxicity according to ISO 10993-5. Tests included covered:
  - non-coated prosthetic screw representative for subject device (test of primary
  - predicate device K190299)
  - Medicarb coated prosthetic screw representative for subject device (test of
  - primary predicate device K171799)
  - Elos Accurate® Customized Abutment representative for subject devices (test of primary predicate device (K171799))
- Sterilization validation according to ISO 17665-1 & ISO 17665-2, demonstrating a SAL of 10^{-6}. (The sterilization and Dry-time studies are conducted on the Primary Predicate Device (K171799) and can be leveraged to the subject Elos Accurate Customized Abutments as material, size and geometry are substantial equivalent)
- The digital dentistry workflow validation was completed on selected model 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 subject abutment design library (not allowing the user to design outside the design limits set by Elos Medtech) to demonstrate use with the 3Shape Abutment Designer™ Software (K151455). The design library file (DME-file) provided by Elos Medtech includes design limits in accordance with *Electronic Package insert - Instruction For Use, Surgical & Prosthetic Guide - In Lab Milling*. The 3Shape Abutment Designer™ Software (K151455) prevents designing outside the specified design limits in the library file.
- Elos Medtech Pinol A/S solely manufactures abutments and screws in TiAl6V4 ELI. The screws are either uncoated or Medicarb coated. The Customized Abutments are delivered uncoated for machining by the dental lab. The screws and abutments are designed to be compatible with many different implant systems from implant manufacturers, which are made of titanium alloys, mostly titanium grade 4 (commercially pure Ti). TiAl6V4 ELI, commercially pure Ti and the used coating does not contain ferromagnetic materials (such as Fe, Co and Ni), meaning that the MRI response will be limited. To verify that a worst-case assembly made of Elos Medtech devices was MR conditional, a range of tests was performed on the worst-case assembly according to ASTM F2052, ASTM F2119, ASTM F2213 and ASTM F2182. The device has been assessed at 1.5 Tesla and 3 Tesla for displacement, torque, heating and image artifact in the MRI scanner, which proved that the proposed devices are MR conditional to use when having an MRI scan.
- To address the potential risk of damage to the implant-abutment connection geometry during the milling of the patient-matched portions of the abutment blanks, validation

testing of CAM restriction zones was conducted, including verification to show avoidance of damage or modification of the connection geometry, and locking of restriction zones from user editing in the CAM software.

XI. Conclusions:

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