February 6, 2020

Elos Medtech Pinol A/S
Tina Poulsen
Head of Compliance
Engvej 33
Goerloese, DK-3330
DENMARK

Re: K191890
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
Dated: January 3, 2020
Received: January 6, 2020

Dear Tina Poulsen:

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: K191890
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.

Elos Accurate Customized Abutment – Model Type	Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
AB-ATO35	Astra Tech 3.5/4.0	3.5 & 4	3.5 & 4
AB-ATO45	Astra Tech 4.5/5.0	4.5 & 5	4.5 & 5
AB-ATE36	Astra Tech EV 3.6	3.6	3.6
AB-ATE42	Astra Tech EV 4.2	4.2	3.6 & 4.2
AB-ATE48	Astra Tech EV 4.8	4.8	4.2 & 4.8
AB-ATE54	Astra Tech EV 5.4	5.4	5.4

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.

Prescription Use__X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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
January 3rd, 2020

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

I. Company:

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DK-3330 Goerloese
Denmark

Contacts:

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Magnus Lynge Bergholt
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E-mail: magnus.jacobsen@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

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

Reference Devices:

- K091239 / SE 09/22/2009 - ASTRA TECH IMPLANT SYSTEM
- K111287 / SE 09/26/2011 - ASTRA TECH IMPLANT SYSTEM
- K171799 / SE 01/15/2018 – Elos Accurate® Customized Abutment
- K120414 / SE 07/31/2012 - OsseoSpeedTM Plus
- K183518 / SE 03/18/2019- Preat Abutments

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 by an Elos Medtech approved milling facility. 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.

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.

Elos Accurate Customized Abutment – Model Type	**Platform compatibility**	**Platform diameter [mm]**	**Implant Body diameter [mm]**
AB-ATO35	Astra Tech 3.5/4.0	3.5 & 4	3.5 & 4
AB-ATO45	Astra Tech 4.5/5.0	4.5 & 5	4.5 & 5
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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.

IX. Summary of the Technological Characteristics:

The subject devices provide additional restorative options for connection to existing implant platforms. The subject devices has similar Indications for Use, intended use, designs, sizes and configurations, materials, and principles of operation as the primary predicate device Elos Accurate® Customized Abutment (K190299 / SE 06/26/2019). 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 are identical except for implant system compatibility. The implant system compatibility of the subject device is extended to include compatibility other implant platforms. The difference in implant system compatibility have been substantiated by engineering and dimensional analysis of original manufactures' components (abutments, implants & abutment screws) for determination of compatibility and fatigue testing.

<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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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.</td></tr>
<tr><td>Primary Predicate Device (K190299)

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.
The Elos Accurate® Customized Abutments are compatible with the implant systems listed in table 1:
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<tr><td>AB-NBR35</td><td>Nobel Replace NP</td><td>3.5</td><td>3.5</td></tr>
<tr><td>AB-NBA30</td><td>Nobel CC 3.0</td><td>3</td><td>3</td></tr>
<tr><td>AB-NBA43</td><td>Nobel CC RP</td><td>3.9</td><td>4.3 & 5</td></tr>
<tr><td>AB-NBA60</td><td>Nobel CC WP</td><td>5.1</td><td>5.5</td></tr>
<tr><td>AB-SBO33</td><td>Straumann Bone Level</td><td>3.3</td><td>3.3</td></tr>
<tr><td>AB-SBO41</td><td>Straumann Bone Level</td><td>4.1 & 4.8</td><td>4.1 & 4.8</td></tr>
</table>
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.</td></tr>
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Element of Comparison	Subject Device Elos Accurate® Customized Abutment	Primary Predicate Device (K190299) Elos Accurate® Customized Abutment
FDA Classification & Product Code	21 CFR 872.3630: NHA Endosseous Dental Implant Abutment	21 CFR 872.3630: NHA Endosseous Dental Implant Abutment
Base Materials	Elos Accurate® Customized Abutments: Titanium Alloy 6Al-4V ELI, medical grade 5 Elos Prosthetic screws: Titanium Alloy 6Al-4V ELI, medical grade 5	Elos Accurate® Customized Abutments: Titanium Alloy 6Al-4V ELI, medical grade 5 Elos Prosthetic screws: Titanium Alloy 6Al-4V ELI, medical grade 5
Surface Finish	Elos Accurate® Customized Abutment: Non-coated Elos Abutment screws: Non-coated	Elos Accurate® Customized Abutment: Non-coated Elos Abutment screws: MediCarb (DLC) Non-coated
Implant interface	Indexed	Indexed
Connection type	Conical	Flat top and conical
Abutment diameter	Ø3.5 – Ø5.4 mm	Ø3.0 – Ø6.0 mm
Prosthesis attachment	Cement-retained	Cement-retained
Restoration	Single-unit &Multi-unit	Single-unit &Multi-unit
Abutment Design Matrix	Up to 30°	Up to 30°
Sterility	Provided non-sterile	Provided non-sterile
Sterilization method	Steam sterilization	Steam sterilization
Digital CAD Systems	510(k) cleared CAD software	510(k) cleared CAD software
Abutment Design Matrix	Minimum wall thickness: 0.4 mm Maximum post height: 13 mm Maximum angulation: 30° Maximum diameter: 12 mm Minimum post height: 4mm Minimum gingiva height: 0.5mm Maximum gingiva height: 5mm	Minimum wall thickness: 0.4 mm Maximum post height: 13 mm Maximum angulation: 30° Maximum diameter: 12 mm Minimum post height: 4mm Minimum gingiva height: 0.5mm Maximum gingiva height: 5mm

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 included:

- engineering and dimensional analysis of original manufactures' components (abutments, implants & abutment screws) for determination of compatibility.
- fatigue testing per ISO 14801 according to FDA guidance for Industry and FDA Staff "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*" dated May 12, 2004.
- 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)
  - Elos accurate® Customized Abutment representative for subject devices (test of reference predicate device (K171799))

  The fatigue test results of the subject devices compatible with Astra Tech 3.5 have been substantiated by the reference predicate device (K183518).

  As the primary predicate device were tested according to ISO 17665-1 & ISO 17665-2, demonstrating a SAL of 10^{-6} no additional testing were necessary on the subject device.

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.