January 23, 2018

Elos Medtech Pinol A/S
Tina Poulsen
RA/QA Manager
Engvej 33
Goerloese, DK-3330
DENMARK

Re: K171799
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: December 11, 2017
Received: December 14, 2017

Dear Tina Poulsen:

This letter corrects our substantially equivalent letter of January 15, 2018.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K171799
Device Name: Elos Accurate® Customized Abutment

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 following implant systems:

Ref. No.	Platform compatibility	Implant diameter
AB-BRA411213-US	Nobel Biocare® / Brånemark® RP	3.75 mm & 4 mm
AB-BRA351213-US	Nobel Biocare® / Brånemark® NP	3.3 mm
AB-BRA511213-US	Nobel Biocare® / Brånemark® WP	5 mm

All digitally designed Elos Accurate® Customized Abutments are intended to be manufactured at an 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
K171799
January 17, 2017

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

I. Company:

Elos Medtech Pinol A/S
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DK-3330 Goerloese
Denmark

Contact:

Tina Friis Poulsen
RA / QA Manager
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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:

- K150203 / SE 10/23/2015 - Medentika PreFace CAD/CAM Abutments

Reference Devices:

- K992538 / SE 11 /23/1999 - AMORPHOUS DIAMOND COATED SCREW
- K062749 / SE 11/29/2006 - SBF 15 ESTHETIC ABUTMENT 1MM NP, MODEL 33699, SFB 15 ESTHETIC ABUTMENT 1MM RP, MODEL 33701, CFB 15 ESTHETIC ABUTMENT 2MM
- K022562 / SE 10/11/2002 - VARIOUS BRANEMARK SYSTEM IMPLANTS-IMMEDIATE FUNCTION INDICATION

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 Brånemark® endosseous 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 following implant systems:

Ref. No.	Platform compatibility	Implant diameter
AB-BRA411213-US	Nobel Biocare® / Brånemark® RP	3.75 mm & 4 mm
AB-BRA351213-US	Nobel Biocare® / Brånemark® NP	3.3 mm
AB-BRA511213-US	Nobel Biocare® / Brånemark® WP	5 mm

All digitally designed Elos Accurate® Customized Abutments are intended to be manufactured at an Elos Medtech approved milling facility.

IX. Summary of the Technological Characteristics:

The subject devices provide additional restorative options for connection to existing Nobel Biocare® Brånemark® implant platform (K022562 / SE 10/11/2002). The subject device has similar Indications for Use, intended use, designs, sizes and configurations, materials, and principles of operation as the primary predicate device Medentika PreFace CAD/CAM Abutments (K150203 / SE 10/23/2015). The subject device also include the Elos Prosthetic Screw with Medicarb coating equivalent to previously cleared reference device #1 (K992538 / SE 11 /23/1999). 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.

The specific language (wording) of the Indications for Use Statements are not identical. However, the subject device and corresponding primary predicates are all abutments intended for use with endosseous dental implants for support of single-tooth or multiple-tooth restorations in the upper or lower arch, and therefore, have the same intended use. The implant system compatibility of the subject device is limited to the Nobel Biocare® Brånemark® NP, RP &WP platforms. However, these are also included for the predicate

device. Also, for the subject device, all digitally designed abutments are intended to be manufactured at an Elos Medtech approved milling facility which is equivalent to the predicate device.

<table>
<tr><th>Element of Comparison</th><th>Indications for Use</th></tr>
<tr><td>Subject Device (K171799)

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 following implant systems:

<table>
<tr><th>Ref. No.</th><th>Platform compatibility</th><th>Implant diameter</th></tr>
<tr><td>AB-BRA411213-US</td><td>Nobel Biocare® / Brånemark® RP</td><td>3.75 mm & 4 mm</td></tr>
<tr><td>AB-BRA351213-US</td><td>Nobel Biocare® / Brånemark® NP</td><td>3.3 mm</td></tr>
<tr><td>AB-BRA511213-US</td><td>Nobel Biocare® / Brånemark® WP</td><td>5 mm</td></tr>
</table>

All digitally designed Elos Accurate® Customized Abutments are intended to be manufactured at an Elos Medtech approved milling facility.</td></tr>
<tr><td>Primary Predicate Device (K150203)

Medentika Preface CAD/CAM Abutments</td><td>Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

<table>
<tr><th>Implant System Compatibility</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare Replace™ Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Nobel Biocare NobelActive™</td><td>F</td><td>3.0, 3.5, 4.3, 5.0</td><td>3.0, 3.5, 3.9 (4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i Osseotite® Certain®</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Nobel Biocare Brånemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr>
<tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Standard</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5(NNC), 4.8, 6.5</td></tr>
<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
</table>

Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.</td></tr>
</table>

Element of Comparison	**Subject Device (K171799)** Elos Accurate® Customized Abutment	**Primary Predicate Device (K150203)** Medentika Preface CAD/CAM Abutments
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	Medentika Preface CAD/CAM Abutments: Titanium Alloy 6Al-4V, medical grade 5 Abutment screws: Titanium Alloy 6Al-4V, medical grade 5
Surface Finish	Elos Accurate® Customized Abutment: Non-coated Elos Abutment screws: MediCarb (DLC)	Medentika Presafe CAD/CAM Abutments: Non-coated Abutment screw: Non-coated
Implant interface	Internal Hexagon on abutment	Internal hexagon on abutment
Connection type	Flat top	Flat top
Abutment diameter	Ø3.5 – Ø5.1 mm	Ø3.5 – Ø5.1 mm
Prosthesis attachment	Cement-retained	Cement-retained
Restoration	Single-unit &Multi-unit	Single-unit & Multi-unit
Abutment Angle	Up to 20°	Up to 30°
Sterility	Provided non-sterile	Provided non-sterile
Sterilization method	Steam sterilization	Steam sterilization
Digital CAD Systems	510(k) cleared CAD software	Straumann® CARES® CAD Software

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
- are to be sterilized using the same processes.

The differences in surface finish and abutment angulation were further supported by:

- evaluation of the abutment screw DLC coating on the subject device according 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 supporting substantial equivalence to the DLC coated abutment screw reference device.

- fatigue test conducted according to ISO 14801 that substantiates an angulation of 20° and the mechanical strength for the subject device.

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.
- sterilization validation were conducted according to ISO 17665-1 & ISO 17665-2, demonstrating a SAL of 10^{-6}.

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.