February 19, 2021

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

Re: K201860
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: January 8, 2021
Received: January 11, 2021

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,

Andrew Steen
Assistant 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: K201860
Device Name: Elos Accurate® Hybrid Base™

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]
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 3.0	3	3
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 3.0	3	3
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

The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ 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, ceramic material, 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® Hybrid Base™
February 19th, 2021

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

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

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Head of Compliance
Tel: +45 27 77 11 17
E-mail: tina.poulsen@elosmedtech.com

Proprietary Trade Name: Elos Accurate® Hybrid Base™

Classification Name: Endosseous Dental Implant Abutment

Classification: Class II, 21 CFR 872.3630

Product Code(s): Primary: NHA
Secondary: PNP

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:
- K191919 / SE 02/10/2020 – Elos Accurate® Hybrid Base™

Reference Devices:
- K180899 / SE 11/01/2018 Universal Base Abutment
- K171799 / SE 01/15/2018 - Elos Accurate® Customized Abutment
- K130436, Multilink Hybrid Abutment Cement, Ivoclar Vivadent AG
- K151455, 3Shape A/S – 3Shape Abutment Designer Software
- K964739 / SE 03/31/1997 – Prosthetic Attachment Screw
- K011394, 3M Lava Plus Zirconia

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™ is used as an interface between a dental implant and a zirconia superstructure and will be attached to the implant using the included prosthetic screw and attached to the zirconia superstructure by 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.
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 (i.e. 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:

1) Minimum wall thickness – 0.5 mm

2) Minimum post height – 4.0 mm (for single unit restorations)

3) Maximum gingival height – 5.0 mm

4) Maximum angulation – 20°

The laboratory designed superstructure is attached to the Elos Accurate® Hybrid Base by use of 510(k) cleared cement (Multilink Hybrid Abutment, K130436) and the final prosthetic restoration is attached to the implant using a Prosthetic screw. The Elos Accurate® Hybrid Base™ 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.

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]
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 3.0	3	3
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 3.0	3	3
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

The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ 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, ceramic material, milling machine and associated tooling and accessories.

Summary of the 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. In order to determine nominal dimensions and tolerances of the Elos Accurate® Hybrid Base™ 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 equivalent except for implant system compatibility and the approach for finalizing the zirconia superstructures. The implant system compatibility of the subject device is extended to include compatibility to the Braanemark implant system platform. 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 (leveraged from K171799) and new fatigue testing (provided with this subject 510(k)).

The subject devices and the primary predicate device are both intended to be used in a digital dentistry workflow which include scanning of patients' teeth setup, designing a zirconia superstructure, manufacturing the superstructure and cementation of the superstructure to the Elos Accurate® Hybrid Base™.

For the Primary Predicate Device (K191919) the digitally designed zirconia superstructures are only intended to be sent and manufactured at an FDA registered Elos Medtech approved milling facility.

For the subject device, the design and fabrication of the zirconia superstructure will be conducted using a digital dentistry workflow requiring the use of following equipment:

- Scanner: 3Shape in scanner (accuracy >10μm)
- Design Software: 3Shape Abutment Designer Software (K151455)
- Zirconia Material: 3M Lava Plus Zirconia (K011394)
- Milling Unit: CORiTEC, Imes-Icore milling unit
- Adhesive material: Multilink Hybrid Abutment Cement, Ivoclar Vivadent AG (K130436)

Both the Reference Devices of K180899 and K151455 are intended to use a digital dentistry workflow by a dental practitioner or dental laboratory outside of an FDA registered approved milling facility to design and manufacture the superstructure component that composes the top half of a two-piece abutment. Thus, the Reference Devices of K180899 and K151455 account for the differences in indications compared to the Primary Predicate Device (K191919) to support substantial equivalence of the digital dentistry workflow of the subject device for the design and fabrication of the zirconia superstructure (K011394) cemented to the Hybrid Base™ for forming a two-piece abutment.

Indications for Use

Subject Device

Elos Accurate® Hybrid Base™

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]
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	3.3	3.3
Straumann Bone	4.1 & 4.8	4.1 & 4.8
Astra Tech 3.0	3	3
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 3.0	3	3
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

The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are only intended to

Indications for Use

Primary Predicate Device (K191919)

Elos Accurate® Hybrid Base™

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 the included 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]
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	3.3	3.3
Straumann Bone Level	4.1 & 4.8	4.1 & 4.8
Astra Tech 3.0	3	3
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 3.0	3	3
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

All digitally designed zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are only intended to be sent and manufactured at an

Indications for Use

Reference Device (K180899)
Universal Base Abutment

The Universal Base Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The Universal Base Abutments consist of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment. The 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.

Compatible Implant platforms listed in table 1.

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Brånemark NP	3.5	3.3
Brånemark RP	4.1	3.75, 4 & 5
Brånemark WP	5.1	5 & 6

Indications for Use

Reference Device (K151455)
3Shape Abutment Designer™ Software

The 3Shape Abutment Designer Software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

Indications for Use Subject Device Elos Accurate® Hybrid Base™	Indications for Use Primary Predicate Device (K191919) Elos Accurate® Hybrid Base™	Indications for Use Reference Device (K180899) Universal Base Abutment	Indications for Use Reference Device (K151455) 3Shape Abutment Designer™ Software
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.	FDA registered Elos Medtech approved milling facility.		

Element of Comparison	Subject Device **Elos Accurate® Hybrid Base™** Elos Medtech Pinol A/S	Primary Predicate Device **K191919** **Elos Accurate® Hybrid Base™** Elos Medtech Pinol A/S	Reference K171799 Elos Accurate® Customized Abutment Elos Medtech Pinol A/S	Reference K180899 Universal Base Abutment Nobel Biocare AB
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	Support of a prosthesis to restore chewing function
Reason for Predicate/Reference	Not applicable	Abutment Design Engineering and dimensional analysis	Engineering and dimensional analysis	digital dentistry workflow
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	Customized abutment mounted on the implant fixed with a screw	2 piece – zirconia bonded to Universal Base Abutment mounted on to the implant and fixed with a screw
Prosthesis Attachment	Abutment screw-retained to implant Superstructure cement-retained	Abutment screw-retained to implant Superstructure cement-retained	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	Single-unit Multi-unit
Abutment/Implant Platform Diameter (mm)	3.0 – 6.0	3.0 – 6.0	3.5 – 5.1	3.5-5.1
Abutment Angle	20° maximum	20° maximum	20°-30°maximum	20° maximum
Ti Base Material	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy
Screw Material	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy
Superstructure Material	3M Lava Plus Zirconia (K011394)	3M Lava Plus Zirconia (K011394)	Not applicable	Enamic (K153645)
Surface	Anodized, non-anodized, Medicarb/DLC coating on screw	Anodized, non-anodized, Medicarb coating on screw	Non-anodized, Medicarb coating on screw	DLC
Design Workflow	3Shape intra oral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455	Elos Medtech approved milling facility.	Elos Medtech approved milling facility.	3Shape intra oral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455
Manufacturing Workflow	CORiTEC milling unit (Imes-Icore)	Elos Medtech approved milling facility.	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.

Discussion of the Non-Clinical Testing:

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

- 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.
- engineering and dimensional analysis of original manufactures' components (abutments, implants & abutment screws) for determination of compatibility.
- Sterilization validation according to ISO 17665-1 & ISO 17665-2, demonstrating a SAL of 10^{-6}.

The digital dentistry workflow validation was completed on selected models 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.
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 June 16. 2016. 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 also leveraged from previously 510(k) cleared products (K171799 and K191919). All tests showed the products to be non-cytotoxic.

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.