September 1, 2023

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

Re: K230317
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: August 4, 2023
Received: August 7, 2023

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: K230317
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]
Zimmer Screw-vent 3.5	Ø3.5	Ø3.7/Ø4.1
Zimmer Screw-vent 4.5	Ø4.5	Ø4.7
Zimmer Screw-vent 5.7	Ø5.7	Ø6.0
Biomet 3i Certain 3.4	Ø3.4	Ø3.25
Biomet 3i Certain 4.1	Ø4.1	Ø4
Biomet 3i Certain 5.0	Ø5	Ø5
Biomet 3i Certain 6.0	Ø6	Ø6
Straumann Standard RN	Ø4.8	Ø3.3/Ø4.1/Ø4.8
Straumann Standard WN	Ø6.5	Ø4.8
Neodent GM	Ø3.5/Ø4.5/Ø5.5/Ø 6.5	Ø3.5/Ø3.75/Ø4/Ø4.3/Ø 5/Ø 6/Ø 7
Hiossen ET Mini	Ø3.2/Ø3.5	Ø3.2/Ø3.5
Hiossen ET Regular	Ø4/Ø4.5/Ø5/ Ø5.5/Ø6/Ø7	Ø4/Ø4.5/Ø5/ Ø5.5/Ø6/Ø7

The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are either intended to be sent and manufactured at an FDA registered Elos Medtech approved milling facility or 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__ 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)

K230317

510(k) Summary
Elos Accurate® Hybrid Base™
Aug. 31st, 2023

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
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DK-3330 Goerloese
Denmark

Contacts:

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II. Proprietary Trade Name: Elos Accurate® Hybrid Base™

III. Classification Name: Endosseous Dental Implant Abutment

IV. Classification: Class II, 21 CFR 872.3630

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

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:
- K201860 / SE 02/19/2021 - Elos Accurate® Hybrid Base™

Reference Devices:
- K191919 / SE 02/10/2020 - Elos Accurate® Hybrid Base™
- K222044 / SE 30/11/2022 - Elos Accurate® Customized Abutment
- K013227 / SE 19/11/2001 - ZimmerBiomet
- K122300 / SE 30/01/2013 - ZimmerBiomet
- K163194 / SE 14/07/2014 - JJGC Industria e Comercio de Materiais Dentarios SA
- K180536 / SE 30/08/2018 - JJGC Industria e Comercio de Materiais Dentarios SA

- K201225 / SE 09/04/2020 - JJGC Industria e Comercio de Materiais Dentarios SA
- K140934 / SE 11/12/2014 - Hiossen Inc.
- K153332 / SE 27/10/2016 - Hiossen Inc.
- K150938 / SE 24/07/2015 - Institut Straumann AG

VII. 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, which when assembled comprises the final finished medical device.

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 (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 (min. GH of 0.5mm)

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 or Panavia V5, K150704) and the final prosthetic restoration is attached to the implant using a Prosthetic screw.

The Elos Accurate® Hybrid Bas has a gold-colored anodized surface to increase the esthetics of the dental restoration - the same surface as in predicate device K201860.

Some of the prosthetic screws are uncoated and two screws are Medicarb coated, identical to the Medicarb coating in predicate device K201860. The subject uncoated screws are compatible with implant platforms Zimmer Screw-vent, Biomet 3i, Neodent GM and Straumann Standard RN and WN. The subject Medicarb coated screws are compatible with the implant platforms Hiossen ET Mini and ET Regular. The purpose of the coating is to lower friction in the thread connection and the screw seat connection.

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.

VIII. 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]
Zimmer Screw-vent 3.5	Ø3.5	Ø3.7/Ø4.1
Zimmer Screw-vent 4.5	Ø4.5	Ø4.7
Zimmer Screw-vent 5.7	Ø5.7	Ø6.0
Biomet 3i Certain 3.4	Ø3.4	Ø3.25
Biomet 3i Certain 4.1	Ø4.1	Ø4
Biomet 3i Certain 5.0	Ø5	Ø5
Biomet 3i Certain 6.0	Ø6	Ø6
Straumann Standard RN	Ø4.8	Ø3.3/Ø4.1/Ø4.8
Straumann Standard WN	Ø6.5	Ø4.8
Neodent GM	Ø3.5/Ø4.5/Ø5.5/Ø 6.5	Ø3.5/Ø3.75/Ø4/Ø4.3/Ø 5/Ø 6/Ø 7
Hiossen ET Mini	Ø3.2/Ø3.5	Ø3.2/Ø3.5
Hiossen ET Regular	Ø4/Ø4.5/Ø5/ Ø5.5/Ø6/Ø7	Ø4/Ø4.5/Ø5/ Ø5.5/Ø6/Ø7

The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are either intended to be sent and manufactured at an FDA registered Elos Medtech approved milling facility or 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.

IX. 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 Hiossen, Neodent, Zimmer, Biomet and Straumann implant system platforms. 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 and new fatigue testing.

The approach of designing and manufacturing the zirconia superstructure for the subject device is either according to a digital dentistry workflow (identical to Primary Predicate Device K201860) or to be sent and manufactured at an FDA registered Elos Medtech approved milling facility (identical

to Reference Device K191919). The subject device does not represent any new worst case, and is thereby covered by existing workflow validation submitted in K201860, except the additional new digital libraries were validated as part of the subject submission, which included following:

- Scanner: 3Shape scanner (accuracy >10µm)
- Design library file (DME-file) provided by Elos Medtech which includes design limits in accordance with "Instruction For Use"
- 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) or Panavia V5 by KURARAY NORITAKE DENTAL (K150704)

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]
Zimmer	Ø3.5	Ø3.7/Ø4.1
Zimmer	Ø4.5	Ø4.7
Zimmer	Ø5.7	Ø6.0
Biomet 3i	Ø3.4	Ø3.25
Biomet 3i	Ø4.1	Ø4
Biomet 3i	Ø5	Ø5
Biomet 3i	Ø6	Ø6
Straumann	Ø4.8	Ø3.3/Ø4.1/Ø4.8
Straumann	Ø6.5	Ø4.8
Neodent GM	Ø3.5/Ø4.5/Ø5.5/Ø 6.5	Ø3.5/Ø3.75/Ø4/Ø4.3/Ø 5/Ø 6/Ø 7
Hiossen ET Mini	Ø3.2/Ø3.5	Ø3.2/Ø3.5
Hiossen ET Regular	Ø4/Ø4.5/Ø5/ Ø5.5/Ø6/Ø7	Ø4/Ø4.5/Ø5/ Ø5.5/Ø6/Ø7

The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are either intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility or 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.

Indications for Use
Primary Predicate Device (201860)

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 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.

Indications for Use
Reference 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 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

All digitally designed zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are only intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility.

Discussion

The Indication for use for the subject device is similar to the Primary Predicate Device (K201860) and Reference Device (K191919), beside table 1. which have been extended with 5 new implant systems, and the approach for finalizing the zirconia superstructure have been merged for the Primary Predicate Device (K201860) and Reference Device (K191919) so the zirconia superstructure either can be manufactured at a FDA registered Elos Medtech approved milling facility or to be designed and manufactured according to digital dentistry workflow.

The difference in implant system compatibility is substantiated by engineering and dimensional analysis of original manufactures' components (abutments, implants & screws) for determination of compatibility and new fatigue testing.

Element of Comparison	**Subject Device** **Elos Accurate® Hybrid Base™** Elos Medtech Pinol A/S	**Primary Predicate Device K201860** **Elos Accurate® Hybrid Base™** Elos Medtech Pinol A/S	**Reference** K191919 **Elos Accurate® Hybrid Base™** Elos Medtech Pinol A/S	**Discussion**
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	Substantial equivalent
Reason for Predicate/Reference	Not applicable	Indication for Use, Abutment Design and manufacturing workflow	Indication for Use, Abutment Design and manufacturing workflow	N/A
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	2 piece – zirconia bonded to hybrid base mounted on to the implant and fixed with a screw	Substantial equivalent
Prosthesis Attachment	Abutment screw-retained to implant Superstructure cement-retained	Abutment screw-retained to implant Superstructure cement-retained	Abutment screw-retained to implant Superstructure cement-retained	Substantial equivalent
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Substantial equivalent
Abutment/Implant Platform Diameter (mm)	3.2 – 7.0	3.0 – 6.0	3.0 – 6.0	Implant diameter for the subject device is up to 7.0mm, which is larger than the primary predicate device. The larger diameter does not represent a new worst case scenario and thereby affect the safety of the product.
Abutment Angle	20° maximum	20° maximum	20°maximum	Substantial equivalent
Materials				
-**Abutment**	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Substantial equivalent
- **Screw**	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Substantial equivalent
-**Zirconia superstructure**	3M Lava zirconia	3M Lava zirconia	3M Lava zirconia	Substantial equivalent
Surface	Abutment: Anodized Screw: Non-coated, Medicarb coated	Abutment: Anodized Screw: Non-coated, Medicarb coated	Abutment: Anodized, non-anodized Screw: Non-coated Medicarb coated	The Subject Abutment is anodized as the predicate abutment. The MediCarb coating is identical

				to the predicate devices. Mechanical perfomance is demonstrated in fatigue testing.
Design Workflow	3Shape intra oral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455	3Shape intra oral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455	Elos Medtech approved milling facility.	Substantial equivalent
Manufacturing Workflow	CORiTEC milling unit (Imes-Icore)	CORiTEC milling unit (imes-icore)	Elos Medtech approved milling facility.	Substantial equivalent

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:

- fatigue testing was performed on the subject devices 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.
- engineering and dimensional analysis of original manufactures' components (abutments, implants & abutment screws) was performed on the subject devices 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 predicate K201860 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 included 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. Since the subject device use identical design and manufacturing workflow (as for the Primary Predicate Device K201860), including identical design limits build in the design library file (DME-file), the subject device does not represent any new worst case, than the worst case documented in

K201860. Hence the new variants are thereby covered by existing workflow validation submitted in K201860. A design limitation test is performed with the purpose of demonstrating in 3Shape Dental System design software, that the user cannot design the zirconia superstructure for Elos Accurate Hybrid base outside the limitations built in the digital libraries relevant for this submission, provided by Elos Medtech.

- 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.
- MR Conditional labeling testing is being leveraged from predicate devices in K222044 and the subject devices do not present a new worst-case for the leveraged testing.

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.