May 17, 2022

Neoss Ltd
% Cherita James
Regulatory Consultant
M Squared Associates Inc.
127 West 30th Street, Floor 9
New York, New York 10001

Re: K211396
Trade/Device Name: Neoss Individual Prosthetics
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 19, 2022
Received: April 21, 2022

Dear Cherita James:

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
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K211396

Device Name

Neoss Individual Prosthetics

Indications for Use *(Describe)*

Neoss Individual Prosthetics are designed to be connected to Neoss Implants and intended for use as an aid in prosthetic rehabilitation.
All digitally designed CAD/CAM customizations for the Neoss Individual Abutments are only intended to be sent to and manufactured by an FDA registered and Neoss approved milling facility. Digital designs for Individual Bars/Bridges are sent to Neoss.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(K) SUMMARY

The following information is provided as required by 21 CFR § 807.87 for the Neoss Individual Prosthetics 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: Neoss Ltd
Windsor House
Cornwall Road
Harrogate, HG1 2PW, UK
Establishment Registration Number: 3005846524

Contact: Cherita James
M Squared Associates, Inc.
127 West 30th St
9th Floor
New York, New York 10001
Ph: 347-954-0624
Fax: 702-562-9797
E-mail: CJames@MSquaredAssociates.com

Date of Submission: May 17, 2022

Proprietary Name: Neoss Individual Prosthetics

Common Name: Dental Implant Abutment

Regulatory Class: II

Regulation: 872.3630

Product Code: NHA

Predicate Device(s): Primary predicate: Neoss Ltd., K043195 Neo Implant System (Neo Mono and Multi abutments, Bar Abutments,)

Reference predicates:

- Neoss Ltd., K071838 Neoss Various Titanium Abutments cleared (Neoss Prepable Abutments);
- Neoss Ltd., K081851 Neoss Access Abutment (Straight and Angled Multi Abutments)
- Neoss Ltd., K090452 Neoss Implant System 3.25 cleared under; (Neoss Implant System Ø3.25 Abutments)

- Neoss Ltd., K150669 Neoss TiBase and CoCr Abutments; (Crystaloc Screw)
- Elos Medtech Pinol A/S, K192457 Elos Accurate® Customized Abutment
- Panthera Dental Inc., K173466 Panthera Dental Milled Bars

Indications for Use: Neoss Individual Prosthetics are designed to be connected to Neoss Implants and intended for use as an aid in prosthetic rehabilitation.
All digitally designed CAD/CAM customizations for the Neoss Individual Abutments are only intended to be sent to and manufactured by an FDA registered and Neoss approved milling facility. Digital designs for Individual Bars/Bridges are sent to Neoss.

Device Description: Neoss Individual Prosthetics are endosseous dental implant abutments used to support single tooth restorations (Abutment) or multi-unit prosthetic restorations (Abutment, Bridge or Bar) on Neoss Implants on implant level or abutment level. Neoss Individual Prosthetics are generally produced with straight screw channels (SSC) to be used with Neo Abutment screws and Neo Screwdrivers. Neoss Individual Prosthetics also features the option to customize the angulation of the screw access channel. Compatible Neoss Implant System includes two implant/prosthetic interfaces, i.e. platforms, SP and NP. Neoss Implant System also includes one abutment/prosthetic interface. This platform is called Access with a platform diameter of 4.0 mm.

	Neoss Implants SP (K043195, K083561, K113376)	**Neoss Implants NP** (K090452)	**Neoss Access Abutments** (K081851)
Neoss Individual Abutments	Compatible	Compatible	Not compatible
Neoss Individual Bridges	Compatible	Compatible	Compatible
Neoss Individual Bars	Compatible	Compatible	Compatible

Neoss Individual **Abutments** are patient specific and are manufactured from Abutment Blanks. Blanks are hollow metal cylinders available in either Titanium (grade 4 ASTM F67 or Ti-6Al-4V alloy ASTM F136). The blank has a precision milled prefabricated Neoss® implant connection (NeoLoc®) for the SP and NP platforms. The top part of the blanks can be milled to a patient-specific shape. The design of the patient-specific shape of the abutment is performed by a licensed clinician or dental technician and then verified for compliance with the abutment design limits by Neoss or a Neoss approved milling facility. Following the verification of the design the CAD/CAM processing and production of the individual prosthetics is conducted by Neoss or a Neoss approved milling facility.
The finished abutment is attached to a Neoss Implant with a screw and a screwdriver at a set torque that depends on the platform.

Neoss Individual **Bridges** are patient specific and are manufactured from bulk material in Titanium (Ti-6Al-4V alloy ASTM F136).The posts that attach to Neoss Implants, optionally with intermediate Neoss Access Abutments, have a pre-defined interface, SP, NP or Access, to assure compatibility. The design of the patient-specific shape of the bridges is performed by a licensed clinician or dental technician and then verified for compliance with the bridge design limits by Neoss. Following the approval of the design, CAD/CAM processing and production of the individual prosthetics is conducted by Neoss. The implant interface is manufactured to Neoss specification to facilitate compatibility with Neoss platforms SP, NP or Access.
The finished bridge is attached to a Neoss Implant or Neoss Access abutment with a screw and a screwdriver at a set torque that depends on the platform.

Neoss Individual **Bars** are patient specific and are manufactured from bulk material in Titanium (Ti-6Al-4V alloy ASTM F136). The posts that attach to Neoss Implants, optionally with intermediate Neoss Access Abutments, have a pre-defined interface to assure compatibility. The bars are designed for use with full or partial removable dentures and can be made with pre-defined design features making them compatible with commercially available precision attachments. The design of the patient-specific shape of the bars is performed by a licensed clinician or dental technician and then verified for compliance with the bar design limits by Neoss. Following the approval of the design, CAD/CAM processing and production of the individual prosthetics is conducted by Neoss. The implant interface is manufactured to Neoss specification to facilitate compatibility with Neoss platforms SP, NP or Access.

The finished bar is attached to a Neoss Implant or Neoss Access abutment with a screw and a screwdriver at a set torque that depends on the platform.

Performance Testing

The Neoss Individual Prosthetics conform to the following standards:

Standard	Recognition Number
ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-258
ISO 14801 Third edition 2016-11-01, Dentistry-Implants-Dynamic fatigue test for endosseous dental implants.	4-259
ISO 14801 Second edition 2007-11-15, Dentistry - Implants-Dynamic fatigue test for endosseous dental implants	4-195
ISO 17665-1, 2006, Sterilization of healthcare products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	14-333

This non-clinical testing data was submitted to demonstrate substantial equivalence:

- engineering analysis and dimensional analysis and;
- static and dynamic compression-bending testing according to ISO 14801 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants.

Biocompatibility: No new biocompatibility testing has been performed, as the subject devices are substantially equivalent to Neo Abutment (K043195) with regards to materials and processing. Biological evaluation reports, cover all materials (titanium grade 4, alloyed titanium) included in Neoss medical devices. The evaluation done within a risk management process as described in ISO 10993-1:2018 is provided for final products, and therefore takes all manufacturing steps into account.

Sterilization validation: Neoss has determined that the Neoss Ti Abutment Blank (K071838) as the worst case product and therefore the validation is applicable also for Neoss Individual Bars and Neoss Individual Bridges, and worst case configuration, with an unprepared Titanium Abutment blank (K150669- Ti Ø3.25 Ø10 x 15) applicable for Individual Abutments.

Clinical Data: Clinical data is not required to establish substantial equivalence in this submission.

Substantial Equivalence

The claim of substantial equivalence of the Neoss Individual Prosthetics to the products identified above is based on the comparison of the intended use, product technical characteristics, performance characteristics and product handling.

Indications for Use

Characteristic	Indications for use
Subject device Neoss Individual Prosthetics	Neoss Individual Prosthetics are designed to be connected to Neoss Implants and intended for use as an aid in prosthetic rehabilitation. All digitally designed CAD/CAM customizations for the Neoss Individual Abutments are only intended to be sent to and manufactured by an FDA registered and Neoss approved milling facility. Digital designs for Individual Bars/Bridges are sent to Neoss.
Primary Predicate Device K043195 Neo Implant System	The Neo Abutments includes a set of components that are intended to function on Neo implants or compatible external hex, Replace Select implants and Straumann implants, as a base prosthetic construction.
Reference Predicate Device	The Neoss Titanium Preparable Abutment 15°and 20° and Neoss Express abutments are **designed to be connected to the Neoss implant and are**

<table>
<tr><td>K071838 Neoss Various Titanium Abutment</td><td>intended for use as an aid in prosthetic rehabilitation.</td></tr>
<tr><td>Reference Predicate Device
K081851 Neoss Access Abutment</td><td>The Neoss Access Abutments are designed to be connected to the Neoss implants and intended for use as an aid in prosthetic rehabilitation.
Neoss Access Abutments represent a two piece abutment system and are designed to be connected to the Neoss implants, to receive another abutment or framework and intended for use as an aid in multiple-unit prosthetic rehabilitation such as dental bridge restorations.</td></tr>
<tr><td>Reference Predicate Device
K090452 Neoss Implant System 3.25</td><td>The Neoss Implant Ø3.25 abutments are designed to be connected to the Neoss implants and intended for use as an aid in prosthetic rehabilitation.</td></tr>
<tr><td>Reference Predicate Device
K150669 Neoss TiBase and CoCr Abutments</td><td>Neoss TiBase:
Neoss Abutments are designed to be connected to the Neoss Implants and intended for use as an aid in prosthetic rehabilitation.
The Neoss TiBase is compatible with the Sirona Dental System inCoris ZI Meso L. All digitally designed copings and/or crowns for use with the Neoss TiBase Abutments are to be designed and milled using the Sirona Dental CAD/CAM System.</td></tr>
<tr><td>Reference Predicate Device
K192457
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:
<table>
<tr><td>Elos Accurate Customized Abutment – Model Type</td><td>Platform compatibility</td><td>Platform diameter [mm]</td><td>Implant Body diameter [mm]</td></tr>
<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</td><td>3.0</td><td>3 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>
<tr><td>Reference Predicate Device
K173466
Panthera Dental Milled Bars</td><td>The Panthera Dental Milled Bar is indicated for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient for purpose of restoring chewing function. It is intended for use to support multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw retained. The Panthera Dental Milled Bars are indicated for compatibility with the Zimmer Tapered Screw-Vent System for sizes 3.5 and 4.5.</td></tr>
</table>

Predicate and Reference Device Comparisons

Neoss Individual Abutments

Characteristic	**Neo Implant System**	**Neoss Titanium Various Abutments**	**Neoss Access Abutment**	**Neoss Implant 3.25 Prepable Abutments**	**Neoss TiBase and CoCr Abutment**	**Elos**	**Neoss Individual Prosthetics** *Subject device*	**Substantially equivalent**
510(k)	K043195	K071838	K081851	K090452	K150669	K192457	To be determined	-
Types of abutments	Abutments for single tooth or cemented bridge	Abutments for single tooth or cemented bridge	Multi-unit abutments (incorporated into bridges) Bar Abutments (welded or soldered to bar constructions)	Abutments for single tooth or cemented bridge	Abutments for single tooth or cemented bridge	Abutments for single tooth or cemented bridge	Abutments for single tooth or cemented bridge	Yes
Characteristics	Customizable to desired shape	Customizable to desired shape	Multi-unit abutment with set of customizable and cast-able bridge and bar abutments	Customizable to desired shape	Customizable to desired shape	Customizable to desired shape	Customizable to desired shape	Yes

Characteristic	Neo Implant System	Neoss Titanium Various Abutments	Neoss Access Abutment	Neoss Implant 3.25 Prepable Abutments	Neoss TiBase and CoCr Abutment	Elos	Neoss Individual Prosthetics *Subject device*	Substantially equivalent
510(k)	K043195	K071838	K081851	K090452	K150669	K192457	To be determined	-
Material	Abutments: Titanium grade 4, ASTM F67 Titanium alloy, ASTM F136 Screws: Titanium alloy, ASTM F136 Gold alloy	Abutments: Titanium grade 4, ASTM F67 Titanium alloy, ASTM F136 Screws: Titanium alloy, ASTM F136 Gold alloy	Abutments: Titanium alloy, ASTM F136 Bridge/Bar Posts Screws: Titanium alloy, ASTM F136	Abutments: Titanium grade 4, ASTM F67 Titanium alloy, ASTM F136 Screws: Titanium alloy, ASTM F136	Abutments: Titanium alloy, ASTM F136 CoCr alloy, ASTM F1537 Screws: Titanium alloy, ASTM F136	Elos Accurate® Customized Abutments: Titanium Alloy 6Al-4V ELI, medical grade 5 Elos Prosthetic screws: Titanium Alloy 6Al-4V ELI, medical grade 5	Abutment: Titanium grade 4, ASTM F67 Titanium alloy, ASTM F136 Screws: Titanium alloy, ASTM F136	Yes. The materials used have been used in the primary predicate device
Surface finish	Abutments: Non-coated Screws: Non-coated	Abutments: Non-coated Screws: Non-coated	Abutments: Non-coated Screws: TiN/Au coated	Abutments: Non-coated Screws: Non-coated	Abutments: Non-coated Screws: TiN/Au coated	Abutment: Non-coated Screws: Non-coated Medicarb (DLC)	Abutment/Bar/Bridge: Non-coated Screws: TiN/Au coated	Abutments/Bar/Bridge: Yes. Screw: Yes. The coating is the same as was introduced with K081851 and further established with K150669.
Platform diameter	4.0 mm (SP)	4.0 mm (SP)	4.0 mm (SP)	3.5 mm (NP)	4.0 mm (SP)	3.5 – 5.1	4 mm (SP); 3.5 mm (NP)	Yes. SP is the same as the primary predicate, and NP is the same as K090452
Minimum post height	4 mm	4 mm	Not defined	4 mm	4 mm	4 mm	4 mm	Yes

Characteristic	Neo Implant System	Neoss Titanium Various Abutments	Neoss Access Abutment	Neoss Implant 3.25 Prepable Abutments	Neoss TiBase and CoCr Abutment	Elos	Neoss Individual Prosthetics *Subject device*	Substantially equivalent
510(k)	K043195	K071838	K081851	K090452	K150669	K192457	To be determined	-
Gingival height	Not defined	Not defined	Not defined	Not defined	0-4mm	0.5-5mm	0.5-4mm	Yes. Within the minimum (0mm) and maximum (5mm) of the predicate devices.
Minimum thickness ***(adjacent to screw seating)***	Not defined	0.5 mm	Not defined	0.5 mm	0.4 mm	0.4 mm	0.5 mm	Yes
Abutment Angulation	0 – 20°	0, °15° and 20°	0-30°	0, °15° and 20°	0 – 20°	0-30°	0 – 30°	Yes
Abutment connection	Internal connection with press-fit of interlocking means	Internal connection with press-fit of interlocking means	Internal connection with and without interlocking means	Internal connection with press-fit of interlocking means	Internal connection with press-fit of interlocking means	Indexed	Internal connection with press-fit of interlocking means	Yes
Abutment screw size	M2 Screw (SP)	M2 Screw (SP)	M2 Screw (SP)	M1.6 screw (NP)	M2 screw (SP)	Not defined	SP: M2 screw NP: M1.6 screw	Yes
Screw Channel	Straight	Straight	0-30°	Straight	Straight	Straight	0 – 25°	Equivalent with K081851 Access Abutment.
Sterility	Non-sterile	Non-sterile	Sterile and Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Yes
Digital CAD Systems	Not specified	Not specified	Not specified	Not specified	Sirona system	510(k) cleared CAD software	510(k) cleared CAD software	Yes

Characteristic	**Neo Implant System**	**Neoss Titanium Various Abutments**	**Neoss Access Abutment**	**Neoss Implant 3.25 Prepable Abutments**	**Neoss TiBase and CoCr Abutment**	**Elos**	**Neoss Individual Prosthetics** ***Subject device***	**Substantially equivalent**
510(k)	K043195	K071838	K081851	K090452	K150669	K192457	To be determined	-
Production	Turned and Milled	Turned and Milled	Turned and Milled	Turned and Milled	Turned and Milled	Turned and Milled	Turned and Milled	Yes

Neoss Individual Bridges and Bars

Bridges and Bars Characteristic	**Neo Implant System**	**Neoss Access Abutment**	**Neoss Implant 3.25 Prepable Abutments**	**Neoss TiBase**	**Panthera**	**Neoss Individual Prosthetics** ***Subject device***	**Substantially equivalent**
510(k)	K043195	K081851	K090452	K150669	K173466	To be determined	-
Types of prosthetics	Multi-unit abutments (incorporated into bridges) Bar Abutments (welded or soldered to bar constructions)	Multi-unit abutments (incorporated into bridges) Bar Abutments (welded or soldered to bar constructions)	Multi-unit abutments (incorporated into bridges) Bar Abutments (welded or soldered to bar constructions)	Multi-unit abutments (incorporated into bridges)	One-piece bar, with integrated abutment interfaces (cylinders)	One-piece bridge with integrated abutment interfaces (posts) One-piece bar, with integrated abutment interfaces (cylinders)	Yes
Characteristics	Customizable to desired shape	Multi-unit abutment with set of customizable and cast-able bridge and bar abutments	Customizable to desired shape	Customizable to desired shape	Individually designed for each patient by order of prescription.	Customizable to desired shape	Yes

Bridges and Bars Characteristic	**Neo Implant System**	**Neoss Access Abutment**	**Neoss Implant 3.25 Prepable Abutments**	**Neoss TiBase**	**Panthera**	**Neoss Individual Prosthetics** ***Subject device***	**Substantially equivalent**
510(k)	K043195	K081851	K090452	K150669	K173466	To be determined	-
Material	Abutments: Titanium alloy, ASTM F136 Screws: Titanium alloy, ASTM F136 Gold alloy	Abutments: Titanium alloy, ASTM F136 Bridge/Bar Posts Screws: Titanium alloy, ASTM F136	Abutments: Titanium alloy, ASTM F136 Screws: Titanium alloy, ASTM F136	Abutments: Titanium alloy, ASTM F136 Screws: Titanium alloy, ASTM F136	Titanium alloy	Bar/Bridge: Titanium alloy, ASTM F136 Screws: Titanium alloy, ASTM F136	Yes. The materials used have been used in the primary predicate device
Surface finish	Abutments: Non-coated Screws: Non-coated	Abutments: Non-coated Screws: TiN/Au coated	Abutments: Non-coated Screws: Non-coated	Abutments: Non-coated Screws: TiN/Au coated	Not defined	Bar/Bridge: Non-coated Screws: TiN/Au coated	Abutments/Bar/Bridge: Yes. Screw: The coating is the same as was introduced with K081851 and further established with K150669.
Platform/Cylinder diameter	4.0 mm (SP)	4.0 mm (SP)	3.5 mm (NP)	4.0 mm (SP)	3 – 8 mm	4 mm (SP); 3.5 mm (NP)	Yes, SP is the same as the primary predicate, and NP is the same as K090452
Minimum post/cylinder height	4 mm	Not defined	4 mm	4 mm	0 mm	5 mm	Yes
Minimum thickness ***(adjacent to screw seating)***	Not defined	Not defined	0.5 mm	0.4 mm	Not defined	1.0 mm	Yes

Bridges and Bars Characteristic	**Neo Implant System**	**Neoss Access Abutment**	**Neoss Implant 3.25 Prepable Abutments**	**Neoss TiBase**	**Panthera**	**Neoss Individual Prosthetics** ***Subject device***	**Substantially equivalent**
510(k)	K043195	K081851	K090452	K150669	K173466	To be determined	-
Bridge/Bar connection	Internal connection with no interlocking means	Internal connection with no interlocking means	Internal connection with no interlocking means	Internal connection with no interlocking means	Not defined	Internal connection with no interlocking means	Yes
Abutment screw size	M2 Screw (SP)	M2 Screw (SP)	M1.6 screw (NP)	M2 screw (SP)	Not defined	SP: M2 screw NP: M1.6 screw	Yes
Screw Channel	Straight	0-30°	Straight	Straight	Not defined	0 – 25°	Equivalent with K081851 Access Abutment.
Minimum cross sections between posts/cylinders	Not defined	Not defined	Not defined	Not defined	Height 2.5mm Width 1.5mm	Height 3 mm Width 2 mm	Yes. Subject device is substantially equivalent to predicate devices.
Span between cylinders	Not defined	Not defined	Not defined	Not defined	0-30 mm	0-30 mm	Yes. Subject device is substantially equivalent to predicate devices.
Minimum cross sections of cantilever	Not defined	Not defined	Not defined	Not defined	Height 2.5mm Width 1.5mm	Height 5 mm Width 3 mm	Yes. Subject device is substantially equivalent to predicate devices.
Maximum cantilever length	Not defined	Not defined	Not defined	Not defined	30 mm	Full arch: 15 mm Partial: 6 mm	Yes. Subject device is substantially equivalent to predicate devices.
Sterility	Non-sterile	Sterile and Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Yes
Production	Turned and Milled	Turned and Milled	Turned and Milled	Turned and Milled	Milled	Milled	Yes

Conclusion

Neoss Individual Prosthetics utilize the same materials, dimensions, platform sizes (SP, NP), attachment, surface finishes as previously cleared Neoss devices. Angulations and minimum heights and thickness are within the same specifications are within the same range as the predicate and reference devices identified. The indications and intended use for the subject and predicate/reference devices, while differing in language used, are all abutments, bars, and bridges intended to aid in prosthetic rehabilitation. The process of determining patient specific requirements and device processing is comparable to other customized reference devices. They are compatible with currently marketed Neoss Implants and abutments. The data presented in this submission demonstrates that the proposed devices are substantially equivalent with respect to fatigue testing performance and intended use. The proposed devices perform as well as the legally marketed predicate devices. Furthermore, the proposed devices do not pose any new or increased risks as compared to the legally marketed predicate devices. Any differences between the subject and predicate device would not render the device NSE, affect the safety or effectiveness, or raise different questions of safety and effectiveness.