DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 8, 2015

Neoss Ltd.
c/o Ms. Cherita James
Regulatory Consultant
M Squared Associates, Inc.
575 8th Avenue, Suite 1212
New York, New York 10018

Re: K150669
Trade/Device Name: Neoss TiBase and CoCr Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: September 8, 2015
Received: September 9, 2015

Dear Ms. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150669

Device Name
Neoss TiBase and CoCr Abutments

Indications for Use *(Describe)*

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.

Neoss CoCr Abutments:
Neoss abutments are designed to be connected to the Neoss Implants and intended for use as an aid in prosthetic rehabilitation.

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

[X] 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
Neoss Ltd.
Neoss TiBase and CoCr Abutments

October 5, 2015

ADMINISTRATIVE INFORMATION

Manufacturer Name: Neoss Ltd.
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: Neoss TiBase and CoCr Abutments
Common Name: Dental Implant Abutment
Classification Name: Endosseous dental implant abutment
Classification Regulations: 21 CFR 872.3630, Class II
Product Code: NHA
Classification Panel: Dental Products Panel
Reviewing Branch: Dental Devices Branch

INTENDED USE

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.

Neoss CoCr Abutments:
Neoss abutments are designed to be connected to the Neoss Implants and intended for use as an aid in prosthetic rehabilitation.

DEVICE DESCRIPTION

Neoss TiBase and CoCr Abutments are endosseous dental implant abutments used to support single tooth or multi-unit prosthetic restorations. All subject abutments have a platform interface that is compatible with Neoss implant diameters Ø3.5-5.5 mm. All

Neoss implant sizes have a 4.1 mm implant platform regardless of endosseous implant diameter. Neoss TiBase abutments are provided in two prosthetic platform sizes, N (narrow) and W (wide), to accommodate different emergence profiles. The Neoss TiBase Abutment are patient specific abutments intended for the coping/crown to be designed using the Sirona CAD/CAM System. The Neoss TiBase Abutment can be screw retained.

Neoss CoCr abutments are available in two designs (Mono and Multi), one prosthetic platform size and one height (15 mm). The indexed Mono abutment can be used for single tooth screw-retained or cement-retained restorations. The non-indexed Multi abutment is used for multi-unit screw-retained restorations.

Neoss Crystaloc screw in TiN/Au coated titanium is used with the Neoss TiBase and CoCr Abutments.

Materials

Neoss TiBase abutment and Crystaloc abutment screws are made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401). Crystaloc Abutment Screw has a TiN surface and is coated with a layer of pure gold. Neoss CoCr Abutments (Mono and Multi) are made of cobalt chromium alloy (CoCr) conforming to ASTM F1537 Standard specification for wrought cobalt-28-chromium-6- molybdenum alloys for surgical implants (UNS R31537, UNS R31538, AND UNS R31539).

Sterilization

Neoss abutments and screws are provided non-sterile. Standard autoclave sterilization is recommended, using fractionated vacuum procedures with an FDA cleared wrap, with an exposure time of 3 minutes at 135 °C / 275 °F with a drying time of 16 minutes. This cycle has been validated by the overkill method to a sterility assurance level (SAL) of 10-6 according to ISO 17665-1.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: engineering analysis, dimensional analysis, and static and dynamic compression-bending testing according to ISO 14801 *Dentistry-Implants-Dynamic fatigue test for endosseous dental implants*. Compatibility with Sirona inCoris blocks is secured by Neoss conducting *re*verse engineering of the Sirona TiBase design mating the inCoris blocks. The compatability is further secured through the fact that the interface between the TiBase and the Sirona inCoris blocks is not a metal-to-ceramic interface, but includes an intervening layer of cement corresponding to a diameter difference of 0.2 mm between the TiBase and the internal geometry of the as-sintered inCoris block which is substantial compared to the small measuring and machining tolerance of TiBase which are ±0.02 mm.

Biocompatibility of the subject devices is confirmed by conformance to FDA recognized consensus material standards (titanium alloy conforming to ASTM F136, and cobalt chromium alloy conforming to ASTM F1537). The manufacturing processes and materials for the Ti Base are identical to those used for Neoss Implant System

components previously cleared in K043195, K071838 and K113376. The pure gold and process used to coat the titanium alloy Crystaloc screw are identical to the titanium and gold screw cleared in K081851. The cobalt chromium alloy (CoCr) material is substantially equivalent to the material used in K121843 NP-Cast Abutment System. No clinical data were included.

EQUIVALENCE TO MARKETED DEVICE

Neoss Ltd. submits the following information in this Premarket Notification to demonstrate, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:
Neoss Ltd., Neo Implant System cleared under K043195; (primary predicate)
Reference Predicates
Neoss Ltd., Neoss Various Titanium Abutments cleared under K071838;
Neoss Ltd., Neoss Tapered Implant cleared under K113376;
Neoss Ltd., Neoss Access Abutments cleared under K081851;
Sirona Dental Systems GmbH, Sirona Dental CAD/CAM System cleared under K111421;
Sirona Dental Systems GmbH, Sirona Dental CAD/CAM System cleared under K100152;
Altatec GmbH, Camlog Implant System Modified Implants and Abutments cleared under K083496; and
OSSTEM Implant Co., Ltd., NP-Cast Abutment System cleared under K121843.

Performance data showed compatibility with the Sirona inCoris ZI Meso L and sufficient strength of the final finished device for its intended use. Any differences in the technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness.

CONCLUSIONS

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including length, width, height, and angle. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Overall, the subject device has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

Substantial Equivalence Tables

Subject Device	Indications for Use Statement
Neoss Ltd. Neoss TiBase and CoCr Abutments	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. Neoss CoCr Abutments: Neoss abutments are designed to be connected to the Neoss Implants and intended for use as an aid in prosthetic rehabilitation.
Predicate Devices	
Neoss Ltd. Neo Implant System K043195 (Primary Predicate)	The Neo Implants - Neo Implant System are for single-stage and two-stage surgical procedures and cement or screw retained restorations. The Neo Implants - Neo Implant System are intended for immediate placement and function on single tooth and /or multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.
Neoss Ltd. Neoss Various Titanium Abutments K071838	The Neoss various Titanium Abutments are designed to be connected to the Neoss implants and intended for use as an aid in prosthetic rehabilitation.
Neoss Ltd. Neoss Tapered Implant K113376	The Neoss Tapered Implant is for single-stage or two-stage surgical procedure and cement or screw retained restorations. The Neoss Tapered Implant is intended for immediate placement and function on single tooth and for multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.
Neoss Ltd. Neoss Access Abutments K081851	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.
Sirona Dental Systems GmbH Sirona Dental CAD/CAM System K111421	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a twopiece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems:

	• Nobel Biocare Replace (K020646) • Nobel Biocare Branemark (K022562) • Friadent Xive (K013867) • Biomet 3i Osseotite (K980549) • Astra Tech Osseospeed (K091239)
Sirona Dental Systems GmbH Sirona Dental CAD/CAM System K100152 Sirona Dental Systems GmbH Sirona CAD/CAM System K100152 (cont.)	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a twopiece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems: • Nobel Biocare Replace (K020646) • Nobel Biocare Branemark (K022562) • Friadent Xive (K013867) • Biomet 3i Osseotite (K980549) • Astra Tech Osseospeed (K091239) • Zimmer Tapered Screw-Vent (K061410) • Straumann SynOcta (K061176)
Altatec GmbH Camlog Implant System Modified Implants and Abutments K083496	Camlog Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. Camlog Implant System Abutments are intended for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.
OSSTEM Implant Co., Ltd. NP-Cast Abutment System K121843	NP-Cast Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

	Subject Device	Predicate Devices							
	Neoss Ltd. Neoss TiBase and CoCr Abutment	Neoss Ltd. Neo Implant System K043195	Neoss Ltd. Neoss Various Titanium Abutment K071838	Neoss Ltd. Neoss Taper Implant K113376	Neoss Ltd. Neoss Access Abutments K081851	Sirona Dental Systems GmbH Sirona Dental CAD/CAM System K111421	Sirona Dental Systems GmbH Sirona Dental CAD/CAM System K100152	Altatec GmbH Camlog Implant System Modified Implants and Abutments	Osstem Implant Co., Ltd NP-Cast Abutment System K121843
Design									
Implant Diameter (mm)	NA	3.5, 4.0, 4.5, 5.0, 5.5	NA	3.5, 4.0, 5.0, 5.5	NA	NA	NA	3.3, 3.8, 4.3, 6.0	NA
Abutment Diameter (mm)	4.1 Interface	4.1 Interface	4.1 Interface	NA	4.1 Interface	3.3, 3.4, 3.5, 3.8, 4.0, 4.1, 4.3, 4.5, 4.8, 5.0, 5.5, 5.7, 6.0, 6.5	3.3, 3.4, 3.5, 3.8, 4.0, 4.1, 4.3, 4.5, 4.8, 5.0, 5.5, 5.7, 6.0, 6.5	3.3, 3.8, 4.3, 6.0	4.0, 4.5, 5.0, 6.3
Abutment Angle	Straight	Straight, 20°	Straight, 15°, 20°	NA	Straight, 10°, 20°, 30°	Straight to 20°	Straight to 20°	Straight, 15°, 20°	Straight to 30°
Prosthesis Attachment	TiBase: Screw CoCr: Screw or Cement	Screw- or Cement retain	Screw- or Cement retain	NA	Screw-retained	Cement - retained	Cement - retained	Screw-retained, Cement-retained	Screw-retained, Cement-retained
Restoration	Single, Multi	Single, Multi	Single, Multi	NA	Multi	Single, Multi	Single, Multi	Single, Multi	Single,Multi
Material									
Abutment	Ti6Al4V, CoCr	CpTi Gr4, Ti6Al4V,	CpTi Gr4, Ti6Al4V	NA	CpTi Gr4, Ti6Al4V, Au	Ti6Al4V, Y-TZP	Ti6Al4V , Y-TZP	CpTi Gr4, Ti6Al4V, Y-TZP,	Co-Cr-Mo Alloy
Abutment Screw	Ti6Al4V, TiN/Au	Ti6Al4V, Au	Ti6Al4V	NA	Ti6Al4V, Au, TiN/Au	Ti6Al4V	Ti6Al4V	Ti6Al4V	Ti6Al4V
Bonding Material	TiBase: PANAVIA F 2.0 (K032455)	NA	PANAVIA F 2.0	NA	NA	PANAVIA F 2.0	PANAVIA F 2.0	NA	NA