July 10, 2019

Dentsply Sirona Inc.
Karl Nittinger
Director, Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K183079
Trade/Device Name: Conometric Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 12, 2019
Received: June 13, 2019

Dear Karl Nittinger:

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,

for Srinivas Nandkumar, Ph.D.
Acting 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

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)*
K183079

Device Name
Conometric Abutments

Indications for Use *(Describe)*
The Conometric Abutments are intended to be used in conjunction with the Conometric Final Cap and Ankylos C/X implants, OsseoSpeed EV implants, and Xive S implants to support fixed friction retained single crowns, in mandible or maxilla, in a partially or completely edentulous patient. This system is intended for delayed loading. The Conometric Abutment including the abutment screw and the Conometric Final Cap make up the final abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

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.

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Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

SECTION 5. 510(k) SUMMARY
for
Conometric Abutments

1.0 Submitter Information**:**

Dentsply Sirona Inc.
221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Karl Nittinger
Telephone Number: 717-487-4424
Fax Number: 717-849-4343

Date Prepared: 9-July-2019

Device Name:

- Proprietary Name: Conometric Abutments
- Classification Name: Endosseous dental implant abutment
- CFR Number: 21 CFR 872.3630
- Device Class: II
- Product Code: NHA (*Abutment, Implant, Dental, Endosseous*)

3.0 Predicate Device:

Predicate Device Name	**510(k)**	**Company Name**
Ankylos® C/X Dental Implant System (Ankylos® Regular Abutments)	K140347	Dentsply Sirona
Reference Device Name	**510(k)**	**Company Name**
Osseospeed Plus	K120414	Dentsply Sirona (former: Astra Tech AB)
XiVE® S plus Dental Implant System	K073075	Dentsply Sirona (former: Friadent GmbH)
Atlantis Abutment for MIS Implant	K172225	Dentsply Sirona

4.0 Description of Device:

The proposed Conometric Abutments are intended for use by dental clinicians in the support of prosthetic dental restorations. The conometric concept provides conical friction retention for fixed single tooth restorations. The Conometric Abutments are provided together with prosthetic conometric caps, impression laboratory devices, and insertion and fixation instruments.

The abutments are provided with an angulation of 0° and 15° at gingival heights of 1.5, 3.0 and 4.5 mm for Ankylos® Conometric Abutments and with 1.0, 2.0 and 3.0 mm for Xive® and Astra Tech Implant System EV® Conometric Abutments. They are manufactured of Titanium Alloy.

The Conometric Final Caps are to be cemented into the final crown to provide friction retention to the abutment. They are made of gold-shaded titanium and are available in the diameter of 3.3 and 4.5 mm.

The Conometric Temporization Caps provide support of immediate and short term provisional prosthetic restorations on Conometric Abutments up to 6 months. The temporary caps are provided with the diameter 3.3 mm and 4.5 mm and are manufactured of PEEK material. The smaller cap (Ø 3.3 mm) also contains titanium alloy.

The Conometric Healing Caps protect the Conometric Abutment until a crown is placed and serve for the shaping of the gingiva. The Healing Caps are made of PEEK polymer and available with an diameter of 3.3 mm and 4.5 mm. Regarding the outer geometries, the Healing Caps are presented as a wide variant with an maximum outer diameter of 6.0 mm and - for the Healing Cap Ø 3.3 mm - also as a small version with an maximum outer diameter of 4.8 mm.

5.0 Indications for Use:

The Conometric Abutments are intended to be used in conjunction with the Conometric Final Cap and Ankylos C/X implants, OsseoSpeed EV implants, and Xive S implants to support fixed friction retained single crowns, in mandible or maxilla, in a partially or completely edentulous patient. This system is intended for delayed loading. The Conometric Abutment including the abutment screw and the Conometric Final Cap make up the final abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

6.0 Substantial Equivalence:

Technological Characteristics:

An overview of the similarities and differences between the subject and predicate devices is given in Table 5.1 below. A discussion of the similarities and differences follows Table 5.1.

Table 5.1: Similarities and Differences between proposed and predicate Conometric Abutments

Element	**Proposed Device** Conometric Abutments	**Predicate Device** Ankylos® C/X Dental Implant System (Ankylos® Regular Abutments) K140347
Manufacturer	Dentsply Sirona	Dentsply Sirona
Indications for Use	The Conometric Abutments are intended to be used in conjunction with the Conometric Final Cap and Ankylos C/X implants, OsseoSpeed EV implants, and Xive S implants to support fixed friction retained single crowns, in mandible or maxilla, in a partially or completely edentulous patient. This system is intended for delayed loading. The Conometric Abutment including the abutment screw and the Conometric Final Cap make up the final abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	ANKYLOS® C/X lmplants of 8 mm in length or longer are for single-stage or two-stage surgical procedures and cemented, removable or screw retained restorations. The ANKYLOS® C/X lmplants may be used for immediate placement and function on single tooth and/or multiple tooth applications when adequate primary stability is achievable, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted. ANKYLOS® C/X lmplants of **6.6 mm in length** are for two-stage surgical procedures and cemented, removable or screw retained restorations. The ANKYLOS® C/X lmplants may be used for immediate placement on single tooth and/or multiple tooth applications when adequate primary stability is achievable, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted.
Intended use of concerned abutments	Prosthetic restoration	Prosthetic restoration
Compatible Implants	Ankylos® C/X Implants (K140347) XiVE® S plus Implants (K073075) OsseoSpeed™ EV Implants (K120414)	Ankylos® C/X Implants (K140347)

Table 5.1: Similarities and Differences between proposed and predicate Conometric Abutments

Element	**Proposed Device** Conometric Abutments	**Predicate Device** Ankylos® C/X Dental Implant System (Ankylos® Regular Abutments) K140347
Implant-Abutment Connection	Ankylos: tapered OsseoSpeed™ EV: tapered XiVE: hexagonal	tapered
Material	Titanium Alloy	Titanium Alloy
Gingiva Height of Abutments	Ankylos®: 1.5mm, 3.0mm, 4.5mm ATIS™ EV: 1.0mm, 2.0mm, 3.0mm XiVE®: 1.0mm, 2.0mm, 3.0 mm	0.75mm, 1.5mm, 3.0mm, 4.5mm
Angulation of Abutments	0°, 15°	0°, 7.5°, 15°, 22.5°
Abutment design	two-piece abutment connected by screw/ one-piece abutment	two-piece abutment connected by screw
Prosthetic restoration	single-unit	single-unit, multi-unit
Fixation of Superstructure	retained by taper friction	screw-retained or cement retained
Sites in the body	Mandible / maxilla	Mandible / maxilla
Reusability	single use	single use
Delivery	Ankylos® and XiVE®: non-sterile OsseoSpeed™ EV: sterile	Implants: sterile Abutments: non-sterile

The indications for use of the subject Conometric Abutments and the predicate device cleared under premarket notification K140347 are similar. Both the subject device and the predicate device (K140347) are intended for single tooth restorations. The indicated use of the subject Conometric Abutments are a subset of those of the predicate device (K140347) in that the predicate device is also indicated for multiple tooth restorations. Though, the indicated use of the Conometric Abutments does not contain reference to proposed implants. Both the subject Conometric Abutments and the abutments of the predicate device system (K140347) are composed of titanium alloy, intended for both maxillary and mandibular use, and are offered in angulations of 0° and 15°. The abutments of the predicate device system are additionally offered in angulations of 7.5° and 22.5°.

While abutments of the predicate device system (K140247) are intended for screw-retained and cement retained restorations, the subject Conometric Abutments are intended for friction retained restorations. Performance testing is included to support substantial equivalence with the respect to the difference in restoration retention.

While the abutments offered with the predicate implant system (K140347) are designed for use with implants of the predicate device system, the subject Conometric Abutments are offered in variants designed for use with implants if the predicate Ankylos C/X Implant System (K140347), as well as, implants of the reference device Osseospeed EV (K120414) and XiVE S (K073075) implant systems. Performance testing is included to support the compatibility of the subject Conometric Abutments, in their worst-case configuration, with the predicate and reference device implants.

7.0 Non-Clinical Performance Data:

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence includes:

- Fatigue Testing: Dynamic fatigue testing was conducted on the worst case construct of the subject abutment (including the Conometric Final Cap) and predicate devices according to ISO 14801 *Dental- implants Dynamic Fatigue Test for Endosseous Dental Implants*
- The friction based retention of the proposed Conometric Abutments was tested under dynamic load. The defined acceptance criteria were fulfilled.
- Pull-out Test: The removal torque of implants after several removal procedures of the Final Cap from the Conometric Abutment have been measured in synthetic bone and compared with test and literature data regarding insertion torque of the Final Cap onto the abutment, removal torques of standard prosthetic restorations (cemented crown) and the pull-out forces of osseointegrated implants. The results showed that the proposed Conometric Abutment system perform as intended.
- Biocompatibility: Material and manufacturing of the proposed Conometric Abutments are identical to those of the predicate device. Thus, biocompatibility data are referenced to support substantial equivalence. Biocompatibility of the Conometric Final Cap, Conometric Temporization Cap and the Conometric Healing Caps, consisting of same material as the predicate devices, have been proved by testing according to ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity and ISO 10993-18 Biological evaluation of medical devices - Part 18: Chemical characterization of materials.
- Sterilization: Sterilization validation of sterile devices is referenced by equivalence (and supported by technical equivalence rationale) to sterilization validation of existing worst-case challenge validations conducted according to ISO 11137-1 *Sterilization of health care products --Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and ISO 11137-2 *Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose* which conclude that a sterility assurance level (SAL) of 10-6 is achieved under the sterilization process parameters utilized.
- Moist heat validation sterilization parameters of non-sterile components were validated by equivalence to sterilization of existing worst-case challenge validations conducted according to ISO 17665-1 *Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices* and ISO17665-2 *Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1*demonstrating a sterility assurance level (SAL) of 10^{-6}.
- Packaging and materials are the same as used for the predicate devices. Thus, shelf life data are referenced to support substantial equivalence.

SECTION 5. 510(k) SUMMARY (continued)

8.0 Clinical Performance Data

No human clinical data was included in this premarket notification to support the substantial equivalence of the subject Conometric Abutments.

9.0 Conclusion Regarding Substantial Equivalence

The proposed Conometric Abutments are endosseous dental implant abutments which are intended to be used by dental clinicians for prosthetic restoration in the maxilla and mandible. The proposed devices incorporate the same fundamental technology and intended use as the predicate device and have been proposed for similar indications for use.

Non-clinical bench testing has been conducted and included in this premarket notification to demonstrate the performance of the proposed Conometric Abutments against their design, functional, and safety requirements. The comparison of the intended use, indications for use, technological characteristics, with the inclusion of the results of nonclinical testing, support a conclusion of substantial equivalence of the Conometric Abutments to the predicate device.