April 1, 2022

Dentsply Sirona
Courtney Clark
Sr. Director of Regulatory Affairs
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K213432
Trade/Device Name: MIS Angulated multi-unit abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 3, 2022
Received: March 4, 2022

Dear Courtney Clark:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213432

Device Name
MIS Angulated multi-unit abutments

Indications for Use *(Describe)*

MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.

Narrow implants (Ø3.30mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.

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

510(k) SUMMARY
for
MIS Angulated multi-unit abutments – K213432

1. Submitter Information:

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

Primary Contact Person: Courtney Clark
Telephone Number: 248-895-4379
Fax Number: 717-849-4343

Date Prepared: April 1, 2022

2. Device Name:

- Proprietary Name: MIS Angulated multi-unit abutments
- Classification Name: Endosseous dental implant abutment
- CFR Number: 872.3630
- Device Class: II
- Product Code: NHA

3. Predicate Device:

The primary predicate and reference devices identified relating to the substantial equivalence for the MIS Angulated multi-unit abutments are:

Primary Predicate Device Name	510(k)	Company Name
MIS V3 Conical Connection Dental Implant System	K163349	MIS Implants Technologies Ltd. (Dentsply Sirona)

Reference Device Name	510(k)	Company Name
MIS C1 Wide Platform Conical Connection Abutment	K172505	MIS Implants Technologies Ltd. (Dentsply Sirona)
MIS Internal Hex Dental Implant System	K180282	MIS Implants Technologies Ltd. (Dentsply Sirona)
Ankylos Balance Base Abutments	K122268	Dentsply Sirona Implants (Dentsply Sirona)

4. Description of Device:

The proposed MIS Angulated multi-unit abutments are endosseous dental implant abutments that are connected to MIS dental implants and used as an aid in prosthetic rehabilitation, for anchoring screw retained multiple-unit restorations.

MIS Angulated multi-unit abutments consist of a one-piece abutment and a prosthetic multi-unit screw, both made of Titanium complying with ASTM F136-13 *(Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (USN R56401)*. The proposed abutments are available in 17° and 30° angulations and connected to the implant by a prosthetic multi-unit screw supplied with the proposed abutments. The proposed abutments are also supplied with a titanium gripping bar used to position the multi-unit abutment on the implant. The proposed abutments are supplied sterile to the user. Table 4.1 below summarizes the main specifications of the proposed MIS Angulated multi-unit abutments and the modifications made.

Table 4.1: Specifications of the Proposed MIS Angulated multi-unit abutments

Element	Specifications	Modifications/Changes
Connection	-Conical (C1, V3) -Internal-hex Connection (SEVEN, Lance +, M4)	Same connections Proposed abutments are compatible with multiple conical and internal-hex connections
Platform	-Narrow Platform (NP) -Standard Platform (SP) -Wide Platform (WP)	New NP for angulated multi-unit abutments
Implant platform diameter	-NP: Ø3.3 mm -SP: Ø 3.75, 3.9, 4.2, 4.3, 5.0 mm -WP: Ø 5.0, 6.0 mm	New NP Other platform diameters remain the same.
Gingival height	-1 and 2 mm for NP -3 mm for SP and WP	New gingival height of 3 mm for SP and WP
Angulations	17° and 30° for all platforms	Same angulations
Prosthetic screw Implant to abutment	-Multi-unit screw for SP and WP: MU-SOP01A (cleared in K163349) -Screw for NP: New, MU-SOPN1A	Same materials and same screw for SP and WP. New multi-unit screw to fit the NP abutments

The proposed MIS cementing cap is a superstructure that has a standard connection design intended to be directly connected to all MIS straight and angulated multi-unit abutments with a prosthetic screw. The proposed cementing cap and prosthetic screw are made of Titanium complying with ASTM F136-13. Multi-unit cementing caps are delivered non-sterile, and are intended to be cleaned and steam-sterilized by a professional user according to the instructions before use.

5. Indications for Use:

MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.30mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to

provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.

6. Substantial Equivalence:

The design of the proposed MIS Angulated multi-unit abutments is based on the design of angulated multi-unit abutments cleared under primary predicate (K163349) and reference devices (K172505, K180282). The abutment diameter, implant-abutment-superstructure connection, and angulations are identical. The proposed MIS Angulated multi-unit abutments include a higher gingival height for Standard and Wide Platforms and are also available in a Narrow Platform.

An overview of the similarities and differences between the proposed and the primary predicate device (K163349) is given in Table 6.1. below. A discussion of the similarities and differences follows Table 6.1.

Table 6.1: Comparison between the proposed MIS Angulated multi-unit abutments and primary predicate device and reference devices

Element	Proposed devices MIS angulated multi-unit abutments and cementing cap	Primary predicate MIS V3 conical connection angulated multi-unit abutments and superstructure (K163349)	Reference device MIS Internal Hex angulated multi-unit abutment (K180282)	Reference device MIS C1 conical connection angulated multi-unit abutment (K172505)	Reference device Ankylos Balance Base angulated multi-unit abutment (K122268)
Indications for Use	MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.30mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.	MIS V3 Conical Connection Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.30mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.	MIS dental implant system is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The angled ANKYLOS® Balance Base Abutments are indicated for use in prosthetic restorations with Ankylos® implants and bridges or bar overdentures using a minimum of 2 implants. In edentulous jaws, immediate loading is possible using a minimum of 4 implants. Implants may be tilted up to 45°. When used with angulations between 30° and 45° in edentulous arch, a minimum of four implants must be used and splinted.
Manufacturer	MIS Implants Technologies Ltd. (Dentsply Sirona)	MIS Implants Technologies Ltd. (Dentsply Sirona)	MIS Implants Technologies Ltd. (Dentsply Sirona)	MIS Implants Technologies Ltd. (Dentsply Sirona)	Dentsply Sirona
Device Class	Class II	Class II	Class II	Class II	Class II
Product code(s)	NHA, Endosseous dental implant abutment	NHA, Endosseous dental implant abutment	NHA, Endosseous dental implant abutment	NHA, Endosseous dental implant abutment	NHA, Endosseous dental implant abutment

Element	**Proposed devices** **MIS angulated multi-unit abutments and cementing cap**	**Primary predicate** **MIS V3 conical connection angulated multi-unit abutments and superstructure (K163349)**	**Reference device** **MIS Internal Hex angulated multi-unit abutment (K180282)**	**Reference device** **MIS C1 conical connection angulated multi-unit abutment (K172505)**	**Reference device** **Ankylos Balance Base angulated multi-unit abutment (K122268)**
Material	Titanium	Titanium	Titanium	Titanium	Titanium
Surface treatment	Polished and anodized / Only polished	Polished and anodized after machined	Polished after machined	Polished and anodized after machined	Polished after machined
Screw connection	One abutment screw for connection of the multi-unit to the implant. Prosthetic screw for connection of the superstructure (cementing cap) to the multi-unit	One abutment screw for connection of the multi-unit to the implant. Prosthetic screw for connection of the temporary superstructure to the multi-unit	One abutment screw for connection of the multi-unit to the implant. Prosthetic screw for connection of the temporary superstructure to the multi-unit	One abutment screw for connection of the multi-unit to the implant. Prosthetic screw for connection of the temporary superstructure to the multi-unit	Abutment screw for connection to the implant. 2-piece abutment, abutment head screws into main abutment body. Prosthetic screw for connection to the abutment
Abutment-superstructure interface	Screw secured, with a plate to plate sealing surface	Screw secured, with a plate to plate sealing surface	Screw secured, with a plate to plate sealing surface	Screw secured, with a plate to plate sealing surface	Screw secured, with a plate to plate sealing surface
Restoration	Multiple-units	Multiple-units	Multiple-units	Multiple-units	Multiple-units
Restoration type	Screw-retained	Screw-retained	Screw-retained	Screw-retained	Screw-retained
Abutment diameter	Ø 4.80	Ø 4.80	Ø 4.80	Ø 4.80	Ø 4.20
Implant to abutment connection	-MIS C1 Conical Connection -MIS V3 Conical Connection -MIS SEVEN Internal Hex -MIS M4 Internal Hex -MIS Lance+ Internal Hex	MIS V3 Conical Connection	MIS M4 Internal Hex MIS SEVEN Internal Hex	MIS C1 Conical Connection	Ankylos A, B, C, D. Conical connection

Element	**Proposed devices** **MIS angulated multi-unit abutments and cementing cap**	**Primary predicate** **MIS V3 conical connection angulated multi-unit abutments and superstructure (K163349)**	**Reference device** **MIS Internal Hex angulated multi-unit abutment (K180282)**	**Reference device** **MIS C1 conical connection angulated multi-unit abutment (K172505)**	**Reference device** **Ankylos Balance Base angulated multi-unit abutment (K122268)**
Implant platform diameter	NP: Ø3.3 mm SP: Ø 3.75, 3.9, 4.2, 4.3, 5.0 mm WP: Ø 5.0, 6.0 mm	NP, WP: N/A SP: Ø 3.75, 3.9, 4.2, 4.3, 5.0 mm	NP: N/A SP: Ø 3.75, 3.9, 4.2, 4.3, 5.0 mm WP: Ø 5.0, 6.0 mm	NP, SP: N/A WP: Ø 5.0, 6.0 mm	A 3.5 B 4.5 C 5.5 D 7
Angulation	NP - 17°, 30° SP & WP - 17°, 30°	NP, WP: N/A SP - 17°, 30°	NP: N/A SP & WP - 17°, 30°	NP, SP: N/A WP - 17°, 30°	15°, 30°
Gingival Height (mm)	NP: 1, 2 SP & WP: 3	NP, WP: N/A SP: 1, 2	NP: N/A SP, WP: 1, 2	NP, SP: N/A WP: 1, 2	3, 4.5 mm
Sterilization	Multi-unit provided sterile by gamma irradiation. Superstructures are provided non-sterile.	Multi-unit provided sterile by gamma irradiation. Superstructures are provided non-sterile.	Multi-unit provided sterile by gamma irradiation. Superstructures are provided non-sterile.	Multi-unit provided sterile by gamma irradiation. Superstructures are provided non-sterile.	Provided non-sterile. User to sterilize via moist steam sterilization

The intended use of the proposed device and the primary predicate MIS V3 Conical Connection Dental Implant Abutment (K163349) is the same. The primary predicate device (K163349) indications for use statement is specific to V3 conical connection implants and is not available in short or long implants. The modifications to the indications for use are supported by the Indications for Use of prior clearances of the additional compatible implant bodies included in this submission. Besides these minor differences, the indications for use are the same.

The proposed MIS angulated multi-unit abutments and the primary predicate abutments (K163349), share a similar design, are made from titanium and are identical in manufacturing processes and facility, packaging, sterilization, and intended use. Both the proposed and primary predicate device (K163349) are connected via a multi-unit screw to MIS Endosseous dental implants to aid in restoration of a partially or fully edentulous jaw and are to be used with angulated screw retained restorations. They are also designed to receive a superstructure as an interface for the final or temporary restoration via a prosthetic screw.

The proposed devices have the same conical standard platform as the primary predicate abutments (K163349) and compatible with MIS V3 Conical Connection implants (K163349). In addition, the proposed MIS angulated multi-unit abutments have the same internal-hex (MIS M4 Internal Hex and MIS SEVEN Internal Hex implants) and conical (MIS C1 Conical Connection wide platform) connection as the reference devices K180282 and K172505, respectively.

The proposed MIS angulated multi-unit abutments are available in higher gingival height and narrower platforms. The reference devices, Ankylos Balance Base abutments (K122268), have a similar angulated screw retained design, are made from Titanium, and are available in angulation of 15° and 30° and gingival heights of 3 and 4.5 mm. The gingival height of the reference device (K122268) and that of the proposed device are nearly identical when measured on the same axis and therefore fatigue testing results of the reference device, Ankylos Balance Base abutments (K122268), was compared to that of the proposed device to demonstrate substantial equivalence. The introduction of the narrow platform was also verified via fatigue testing and it was confirmed that the results are substantially equivalent to the reference device Ankylos Balance Base abutments (K122268).

Both primary predicate temporary superstructure (K163349) and the proposed cementing cap share the same raw material, manufacturing process, surface treatment, and packaging. The difference between the two superstructures is that the proposed cementing cap is intended to be used for permanent restorations while the primary predicate temporary superstructure (K163349) is intended to be used for temporary restorations for up to 180 days. Both are attached to the multi-unit using the same prosthetic screw, and share an identical interface to the multi-unit. The fatigue testing performed on the proposed MIS Angulated multi-unit abutments included the proposed cementing cap in the implant-abutment combination and the results show acceptable fatigue results that are substantially equivalent to the reference device Ankylos Balance Base abutment (K122268).

7. Non-Clinical Performance Data

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

- Fatigue Testing: Guidance document "Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Class II Special Controls" and ISO 14801:2016 *(Dentistry - Implants-Dynamic fatigue tests for endosseus dental implants)* was used for determining the performance testing required for the proposed device, MIS Angulated multi-unit abutments.

  Mechanical testing of representative worst-case MIS Angulated multi-unit abutment-implant combinations were included. The test articles were able to withstand 5,000,000 cycles without failure at a substantially equivalent load or better, compared with the reference device (K122268).

- Sterilization:
  - Sterilization validation of sterile devices was submitted to demonstrate sterilization validation of existing worst-case challenge validations conducted according to ISO 11137-1:2006/(R)2013 (*Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*), ISO 11137-2:2013 (*Sterilization of health care products, Radiation- Part 2: Establishing the sterilization dose*), and ISO 11737-2:2009 (*Sterilization of medical devices – Microbiological methods- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*). The sterilization with a sterilization dose of 20 kGy provides a sterility assurance level (SAL) of 10^{-6}.
  - Steam sterilization validation of non-sterile devices was submitted to demonstrate sterilization validation of gravity displacement and pre-vacuum methods according to ANSI/AAMI/ISO 17665-1:2006/(R)2013 (*Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*), ANSI/AAMI/ISO 17665-2:2009 (*Sterilization of health care products – Moist heat- Part 2:Guidance on the application of ISO/ANSI/AAMI/ISO 17665-1*), and ISO 11138-1:2017 (*Sterilization of health care products – Biological indicators – Part 1 General requirements*).

- Shelf life: Shelf life study of sterile devices is referenced by equivalence to real time aging study performed (submitted in K180282) according to ISO 11607-1:2019 *(Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems)*. Test results support a 5-year shelf life.

- Biocompatibility: The proposed MIS Angulated multi-unit abutment devices are manufactured using identical manufacturing methods, in the same manufacturing facility, and

using the same raw material and packaging materials as the primary predicate (K163349) devices. The proposed device has the same contact classification and duration as the primary predicate (K163349), which is direct contact, permanent duration (>30 days). It was determined that no new biocompatibility testing was required to support substantial equivalence of the proposed device.

8. Clinical Performance Data

No human clinical data was included to support substantial equivalence.

9. Conclusion Regarding Substantial Equivalence

The information included in this premarket notification supports the substantial equivalence of the proposed MIS Angulated multi-unit abutments with the primary predicate device MIS V3 conical connection angulated multi-unit abutments (K163349). The proposed devices have the same intended use, principles of operation, manufacturing and packaging processes, packaging materials, and sterilization, very similar indications for use, and similar performance characteristics as the legally marketed primary predicate device (K163349). The modification to add a narrow platform and additional gingival height was confirmed via fatigue performance testing and supports a conclusion that the proposed devices are substantially equivalent to the predicate devices.