March 25, 2020

Dentsply Sirona
Karl Nittinger
Vice President, Corporate Regulatory Affairs
221 W Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K193078
Trade/Device Name: MIS CONNECT Conical Connection System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 2, 2020
Received: March 2, 2020

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.
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)*

K193078

Device Name

MIS CONNECT Conical Connection System

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 (Ø3.3mm) 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.

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

510(k) SUMMARY
K193078
MIS CONNECT Conical Connection System

1.0 Submitter Information:

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

Contact Person: Karl Nittinger
Email: karl.nittinger@dentsplysirona.com
Telephone Number: 717-487-4424
Fax Number: 717-849-4343
Date Prepared: 06 March 2020

2.0 Device Name:

- Proprietary Name: MIS CONNECT Conical Connection System
- Classification Name: Endosseous dental implant abutment
- CFR Number: 21 CFR 872.3630
- Device Class: Class II
- Product Code: NHA

3.0 Predicate Device:

Primary Predicate Device Name	**510(k)**	**Company Name**
MIS CONNECT Conical Connection abutment	K173326	MIS Implants Technologies Ltd. (Owner/Operator : Dentsply Sirona)
Reference Devices:	**510(k)**	**Company Name**
MIS V3 Cement Retained Abutment	K163349	MIS Implants Technologies Ltd. (Owner/Operator : Dentsply Sirona)
MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments	K172505	MIS Implants Technologies Ltd. (Owner/Operator : Dentsply Sirona)
MIS Conical Connection Implants (Included as a referenced device solely for identification as the compatible implant system).	K112162	MIS Implants Technologies Ltd. (Owner/Operator : Dentsply Sirona)

4.0 Device Description

The proposed devices consist of dental abutments and superstructures and represent a line extension to the MIS CONNECT Conical Connection System.

4.1 **MIS CONNECT Conical Connection Abutments**

The proposed MIS CONNECT Conical Connection Abutments are intended for use by dental clinicians in the support of prosthetic dental restorations in the upper or lower jaw and used in conjunction with MIS conical connection implants, MIS V3 and MIS C1 (K163349 and K112162, respectively).

The abutment is placed above the bone level and within the gingival tissue, and is designed to be fitted with a variety of complementary abutment superstructures, including healing caps, temporary abutments, aesthetic abutments, final abutments, and angulated abutments. Prosthetic screws are included as a system component for use with the subject abutments.

Once connected to the implant, the MIS CONNECT Conical Connection Abutment is not intended to be removed.

The abutments are provided in 4.0 and 5.7 mm platform diameters, with an angulation of up to 20º, and at gingival heights of 1.5, 2.0, 3.0, and 4.0 mm.

4.2 **MIS CONNECT Conical Connection Superstructures**

The proposed MIS CONNECT Conical Connection Superstructures are mounted over the proposed and predicate MIS CONNECT Conical Connection Abutment (Ø4 mm or Ø5.7 mm) and intended for use as an aid in prosthetic dental restoration. The proposed superstructures consist of healing caps, temporary abutments, aesthetic abutments, final abutments, and angulated abutments. Prosthetic screws are included as a system component for use with the subject superstructures.

5.0 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 (Ø3.3 mm) 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.

6.0 Substantial Equivalence Discussion

6.1 **MIS CONNECT CONICAL CONNECTION ABUTMENTS**

A summary of the similarities and differences between the proposed and predicate abutment devices is given in Table 6.1 below. A discussion of the similarities and differences follows Table 6.1.

Table 6.1: Similarities and Differences between the proposed and predicate Abutment devices			
Element	**MIS CONNECT Conical Connection abutments** **Proposed device**	**MIS CONNECT Conical Connection abutments K173326** **Primary Predicate Device**	**MIS V3 Cement Retained Abutments K163349** **Reference Device**
Pictorial Representation			
Intended use:	Dental implant abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function. The MIS CONNECT abutments in combination with endosseous implants are indicated for single or multiple unit reconstructions when screw retained prosthetics are preferred.	Dental implant abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function. The MIS CONNECT abutments in combination with endosseous implants are indicated for single or multiple unit reconstructions when screw retained prosthetics are preferred.	Dental implant abutments are intended to be used in the upper or lower jaw used for supporting tooth replacements to restore chewing function. The abutments in combination with two-stage endosseous implants are intended to be used as a foundation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement-retained supra-constructions.
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 (Ø3.3mm) 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 (Ø3.3mm) 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 System 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 (Ø3.3mm) 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
Material(s)	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136

Table 6.1 (continued): Similarities and Differences between the proposed and predicate Abutment devices			
Element	**MIS CONNECT Conical Connection abutments** **Proposed device**	**MIS CONNECT Conical Connection abutments K173326** **Primary Predicate Device**	**MIS V3 Cement Retained Abutments K163349** **Reference Device**
Surface Treatment	Anodized after machining	Anodized after machining	Polished and anodized after machining
Type of Connection to the Implant	Conical connection without indexes	Conical connection without indexes	Conical connection NP: 3 indexes SP: 6 indexes
Type of Connection to the Superstructure	Internal connection Anti-rotation: 12 indexes Free-rotation: no indexes	Internal connection Anti-rotation: 3 indexes Free-rotation: no indexes	NA – the crown is cemented directly onto the abutment post.
Compatible implant platforms	MIS CONNECT Ø4 abutment: NP, SP, WP MIS CONNECT Ø5.7 abutment: SP, WP	NP, SP, WP	NP, SP, WP
Gingival Height	NP: 2, 3 mm SP: 1.5, 2, 3, 4 mm WP: 1.5, 2, 3, 4 mm	NP: 2, 3 mm SP: 1.5, 2, 3, 4 mm WP: 1.5, 2, 3, 4 mm	0.5, 1, 1.5, 2, 3 mm
Post height	NA – the MIS CONNECT does not have a post for prosthetic reconstruction, but is configured to be mounted with a superstructure having a post.	NA – the MIS CONNECT does not have a post for prosthetic reconstruction, but is configured to be mounted with a superstructure having a post.	8 mm
Diameter	NP: 4 mm SP/WP: 4mm, 5.7 mm	NP/SP/WP: 4 mm	NP: 4.0, 4.25, 4.8 mm SP: 4.25, 4.8, 5.8 mm
Sterilization Method	Radiation	Radiation	Product provided non sterile and end-user sterilized.

The proposed MIS CONNECT Conical Connection Abutments when compared to the predicate device, MIS CONNECT Conical Connection abutment**,** are identical with respect to indications for use, material composition, and general principles of operation. The proposed and predicate devices are intended for prosthetic restoration in the maxillary and mandible and are offered in 4 mm diameters.

While the abutments in the predicate are only available in 4 mm diameter, the proposed abutments are available in both 4 mm and 5.7 mm diameters. The reference device (K163349) is included in support of substantial equivalence as it includes a maximum diameter abutment of 5.8 mm. While the abutments in the originally cleared predicate device have 3 indexes anti-rotation connection with the superstructure, the proposed abutments have 12 indexes anti-rotation connection, allowing enhanced precision for rotational positioning of the restoration. The increased number of rotational indexes does not impact substantial equivalence as the modification does not affect abutment wall thickness and therefore does not present a new worst case with respect to connection geometry.

Performance testing (Fatigue testing) is included in this premarket notification to support the substantial equivalence of the proposed devices to the predicate device.

6.2 Line extension to predicate **MIS CONNECT Conical Connection Superstructures:**

An overview of the similarities and differences between the proposed and predicate Superstructure devices is given in Tables 6.2a - 6.2e below. A discussion of the similarities and differences follows Table 6.2a – 6.2e.

Table 6.2a: Comparison of the proposed device to the predicate device (Healing Caps)

Element	MIS CONNECT Healing Caps **Proposed device**	MIS CONNECT Healing Caps K173326 **Primary Predicate Device**	MIS V3 Healing Caps K163349 **Reference Device**
Pictorial Representation			
Material(s)	TI 6Al-4V ELI per ASTM F136.	TI 6Al-4V ELI per ASTM F136.	TI 6Al-4V ELI per ASTM F136.
Surface Treatment	Anodized after machining	Anodized after machining	Polished and anodized after machining
Connection interface	Compatible with MIS CONNECT abutment	Compatible with MIS CONNECT abutment	Compatible with MIS Conical Connection implants
Type of Connection to the MIS CONNECT abutment	Internal connection Without indexes	Internal connection Without indexes	NA - connects directly to the implant in an internal connection without indexes
Gingival Height	Ø4: 0.5, 1.5, 3 mm Ø5.7: 0.5, 1.5, 3 mm	Ø4: 0.5, 1.5 mm	2, 3, 4, 5, 6, 8 mm
Post Height	NA – the device is not intended to serve as a basis for prosthetic reconstruction	NA – the device is not intended to serve as a basis for prosthetic reconstruction	NA – the device is not intended to serve as a basis for prosthetic reconstruction
Diameter	4mm, 5.7 mm	4 mm	3.3-5.8 mm
Sterilization Method	Radiation	Radiation	Radiation

Table 6.2b: Comparison of the proposed device to the predicate device (Temporary Abutment Superstructure)

Element	MIS CONNECT Temporary abutments **Proposed Device**	MIS CONNECT Temporary abutments K173326 **Primary Predicate Device**	MIS V3 Temporary abutments K163349 **Reference Device**
Pictorial Representation			
Material(s)	Abutment: Ti-6Al-4V ELI per ASTM F136 Prosthetic screw: Ti 6Al 4V ELI per ASTM F136	Abutment: Ti-6Al-4V ELI per ASTM F136 Prosthetic screw: Ti 6Al 4V ELI per ASTM F136	Abutment: Ti-6Al-4V ELI per ASTM F136 Prosthetic screw: Ti 6Al 4V ELI per ASTM F136
Connection interface	Compatible with MIS CONNECT abutment	Compatible with MIS CONNECT abutment	Compatible with MIS Conical Connection implants
Type of Connection to the MIS CONNECT abutment	Anti-rotation: regular hexagon Free-rotation: no hexagon	Anti-rotation: irregular hexagon Free-rotation: no hexagon	NA – Connects directly to the implant
Gingival Height	N/A – connects to the MIS CONNECT abutment	N/A – connects to the MIS CONNECT abutment	1, 2, 3 mm
Post Height	10 mm	10 mm	10, 10.5mm
Diameter	4mm, 5.7 mm	4 mm	4.0, 4.8, 5.8 mm
Sterilization	Product provided non-sterile and end-user sterilized.	Product provided non-sterile and end-user sterilized.	Product provided non-sterile and end-user sterilized.

Table 6.2c: Comparison of the proposed device to the predicate device (Final Esthetic Abutment Superstructure)

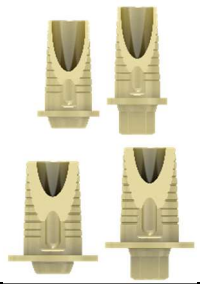
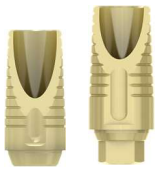
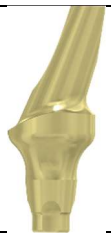
Element	MIS CONNECT Final Esthetic Abutments **Proposed device**	MIS CONNECT Cementing Cap Abutments K173326 **Primary Predicate Device**	MIS V3 Cement Retained Abutments K163349 **Reference Device**
Pictorial Representation			
Material(s)	Abutment: Ti-6Al-4V ELI per ASTM F136 Prosthetic screw: Ti 6Al 4V ELI per ASTM F136	Abutment: Ti-6Al-4V ELI per ASTM F136 Prosthetic screw: Ti 6Al 4V ELI per ASTM F136	Abutment: Ti-6Al-4V ELI per ASTM F136 Prosthetic screw: Ti 6Al 4V ELI per ASTM F136
Connection interface	Compatible with MIS CONNECT abutment	Compatible with MIS CONNECT abutment	Compatible with MIS Conical Connection implants
Type of Connection to the MIS CONNECT abutment	Anti-rotation: regular hexagon Free-rotation: no hexagon	Anti-rotation: irregular hexagon Free-rotation: no hexagon	NA - Connects directly to the implant
Gingival Height	N/A – connects to the MIS CONNECT abutment	N/A – connects to the MIS CONNECT abutment	0.5, 1, 1.5, 2, 3 mm
Post Height	6.05 mm	6.05 mm	5.95 mm
Diameter	4mm, 5.7 mm	4 mm	NP: 4.0, 4.25, 4.8 mm SP: 4.25, 4.8, 5.8 mm
Sterilization	Product provided non-sterile and end-user sterilized.	Product provided non-sterile and end-user sterilized.	Product provided non-sterile and end-user sterilized.

Table 6.2d: Comparison of the proposed device to the predicate device (Final Abutment Superstructure)

Element	MIS CONNECT Final Abutments **Proposed Device**	MIS CONNECT Cementing Cap Abutments K173326 **Primary Predicate Device**	MIS V3 Cement Retained Abutments K163349 **Reference Device**
Pictorial Representation			
Material(s)	Abutment: Ti-6Al-4V ELI per ASTM F136 Prosthetic screw: Ti 6Al 4V ELI per ASTM F136	Abutment: Ti-6Al-4V ELI per ASTM F136 Prosthetic screw: Ti 6Al 4V ELI per ASTM F136	Abutment: Ti-6Al-4V ELI per ASTM F136 Prosthetic screw: Ti 6Al 4V ELI per ASTM F136
Connection interface	Compatible with MIS CONNECT abutment	Compatible with MIS CONNECT abutment	Compatible with MIS Conical Connection implants
Type of Connection to the CONNECT abutment	Anti-rotation: regular hexagon Free-rotation: no hexagon	Anti-rotation: irregular hexagon Free-rotation: no hexagon	NA - Connects directly to the implant
Gingival Height	N/A – connects to the MIS CONNECT abutment	N/A – connects to the MIS CONNECT abutment	0.5, 1, 1.5 ,2 ,3 mm
Post Height	For Ø4: 8 mm For Ø5.7: 4 mm	6 mm	5.95 mm
Diameter	4mm, 5.7 mm	4 mm	NP: 4.0, 4.25, 4.8 mm SP: 4.25, 4.8, 5.8 mm
Sterilization	Product provided non-sterile and end-user sterilized.	Product provided non-sterile and end-user sterilized.	Product provided non-sterile and end-user sterilized.

Table 6.2e: Comparison of the proposed device to the reference device (Angulated Abutment Superstructure)		
Element	**MIS CONNECT Ø4 Angulated Abutments Proposed Device**	**MIS C1 Conical Connection Cement Retained Abutment K172505 Reference Device**
Pictorial Representation		
Material(s)	Abutment: Ti-6Al-4V ELI per ASTM F136 Prosthetic screw: Ti 6Al 4V ELI per ASTM F136	Abutment: Ti-6Al-4V ELI per ASTM F136 Prosthetic screw: Ti 6Al 4V ELI per ASTM F136
Surface Treatment	Polished and anodized after machining	Polished and anodized after machining
Connection interface	Connects to an MIS CONNECT abutment	Connects directly to the implant
Type of Connection to the MIS CONNECT abutment	Anti-rotation: regular hexagon No free-rotation is available	NA – connects directly to the implant
Platform	Connects to MIS CONNECT Ø4 abutment	Connects directly to NP conical connection implants
Gingival Height	N/A – connects to MIS CONNECT abutment	0.5,1,1.5,2,3 mm
Post Height	6 mm / 7 mm (Dependent on gingival collar thickness)	6 mm / 7 mm (Dependent on gingival collar thickness)
Diameter	4 mm	NP: 4.0, 4.2, 4.25, 4.8 mm
Abutment angulation	20°	NP: 0°, 10°, 20°
Sterilization Method	Product provided non sterile	Product provided non sterile

The proposed MIS CONNECT Conical Connection Superstructures are substantially equivalent to the predicate device with respect to indications for use, principles of operation, and materials of construction.

The proposed and predicate devices have identical indications for use, are made of titanium alloy, and are intended for prosthetic restoration of maxillary and mandible.

While the Abutment Superstructures in the predicate device are only compatible with 4 mm diameter abutments (platform diameter), the proposed Abutment Superstructures are compatible with either 4 mm or 5.7 mm diameter abutments. The reference device (K163349) is included in support of substantital equivalence as it includes abutment superstructures with maximum 5.8 mm platform diameter.

While the predicate abutment superstructures connected to the MIS CONNECT Conical Connection Abutment via 3 indexes of anti-rotation, the proposed abutment superstructures connect to the MIS CONNECT Conical Connection Abutment via 12 indexes of anti-rotation in order to enhance rotational precision. The increased number of rotational indexes does not impact substantial equivalence as the modification does not affect abutment wall thickness and therefore does not present a new worst case with respect to connection geometry.

The proposed angulated abutment supersructures are offered with a 20° angulation. Reference device K172505 is included in support of substantial equivalence as it is offered in angulations up to 20°.

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 of worst case representative samples of the proposed MIS CONNECT Conical Connection Abutments (line extension to the predicate) and superstructures was performed in accordance to ISO 14801:2016 *Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants*. The results of the fatgue testing support substantial equivalence.

- Biocompatibility: The proposed devices are composed of the identical materials and are manufactured in the identical manufacturing facility and under the identical manufacturing processes as the primary predicate device (K173326). In addition, the intended conditions of use and patient contact type and duration of contact (as per ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*) for the proposed devices are identical to that of the primary predicate device (K173326). Therefore, no new biocompatibility data are included in support of substantial equivalence.

- Sterilization: Sterilization validation of sterile devices was conducted for worst-case construct according to ISO 11137-2:2013, *Sterilization of health care products- Radiation- Part 2: Establishing the sterilization dose*. The results of the sterilization validation support a conclusion that a sterility assurance level (SAL) of 10^{-6} is achieved under the sterilization parameters utilized.

  Sterilization validation of non-sterile devices was conducted for worst-case construct 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.* The results of the sterilization validation support a conclusion that a sterility assurance level (SAL) of 10^{-6} is achieved under the sterilization parameters utilized by the end-user.

- Packaging and packaging materials are the identical for the predicate and proposed devices. Thus, shelf life data are referenced by equivalence to support substantial equivalence.

8.0 Clinical Performance Data

No human clinical data were included in this premarket notification to support the substantial equivalence of the proposed line extension to predicate MIS CONNECT Conical Connection Abutments.

9.0 Conclusion Regarding Substantial Equivalence

The proposed line extension to predicate MIS CONNECT Conical Connection Abutments are endosseus abutments and abutment superstructures which are intended to be used by dental clinicians for prosthetic restoration in the maxilla and mandible. The proposed devices incorporate the identical fundamental technology and intended use as the predicate MIS CONNECT Conical Connection Abutments and Superstructures device (K173326) and are proposed for identical indications for use. The identical materials of construction (Titanium alloy) and manufacturing processes are used to manufacture the proposed and predicate devices. Fatigue testing of the proposed device is included and the results support substantial equivalence.

The proposed angulated abutment superstructures are similar in design to the reference device MIS C1 Conical Connection Cement Retained Abutment (K172505). The proposed MIS CONNECT angulated abutment's angulation and diameter is within range of design offerings of the reference device (K172505).

The increased abutment diameter to 5.7 mm for the propsoed abutment and abutment superstructures is within range of the reference device MIS Cement Retained Abutments and Superstructures (K163349).

The comparison of the indications for use, technological characteristics, with the inclusion of the results of nonclinical testing, support a conclusion of substantial equivalence of the proposed MIS CONNECT Conical Connection Abutments and Superstructures to the predicate devices.