March 5, 2020

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

Re: K193529
Trade/Device Name: ATLANTIS® Abutment for MIS Conical Connection Implants
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 19, 2019
Received: December 20, 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.
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)*
K193529

Device Name
ATLANTIS® Abutment for MIS Conical Connection Implants

Indications for Use *(Describe)*
The ATLANTIS® Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS® Abutment to the endosseous implant.

The ATLANTIS® Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS® Crown Abutment to the endosseous implant.

The ATLANTIS® Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS® Conus Abutment to the endosseous implant.

The ATLANTIS® Healing Abutment can be used with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The abutment screw is intended to secure the ATLANTIS® Healing Abutment to the endosseous implant.

ATLANTIS® Abutment is compatible with MIS Conical Connection implant from MIS Implant System.

ATLANTIS® products are compatible with the implants shown in the table below.

Implant manufacturer - MIS-IMPLANT TECHNOLOGIES INC

Trade Name	Abutment Platform Diameter	Implant Diameter
Atlantis Abutment for MIS V3 NP	Ø2.765mm	V3: Ø3.30 mm
Atlantis Abutment for MIS C1 NP	Ø2.76mm	C1: Ø3.30 mm
Atlantis Abutment for MIS C1 & V3 SP	Ø3.16mm	C1: Ø3.75,4.2 mm, V3: Ø3.90,4.3,5.0 mm
Atlantis Abutment for MIS C1 WP	Ø4.01mm	C1: Ø5.0 mm

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
K193529
ATLANTIS Abutment for MIS Conical Connection Implants

1. Submitter Information:

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

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
Fax Number: 717-849-4343
Date Prepared: 05 March 2020

2. Device Identification:

- Proprietary Name: ATLANTIS® Abutment for MIS Conical Connection Implants
- Classification Name: Endosseous dental implant abutment
- CFR Number: 21 CFR 872.3630
- Device Class: Class II
- Product Code: NHA

3. Predicate Device:

Predicate Device Name	**510(k)**	**Company Name**
ATLANTIS® Abutment for MIS Implant	K172225	MIS Implants Technologies LTD (Dentsply Sirona)
Reference Devices:		
ATLANTIS® Abutment for HIOSSEN ET Implant	K160626	Dentsply Sirona Implants
MIS V3 Conical Connection Dental Implant System	K163349	MIS Implants Technologies LTD (Dentsply Sirona)
MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutment	K172505	MIS Implants Technologies LTD (Dentsply Sirona)
MIS C1 Standard Platform Conical Connection Dental Implant system MIS C1 Wide Platform Conical Connection Dental Implant system	K112162	MIS Implants Technologies LTD (Dentsply Sirona)

The proposed ATLANTIS® Abutments for MIS Conical Connection Implant are compatible with Implant Systems cleared in the reference devices K172505, K112162, and K163349.

4. Device Description

The proposed ATLANTIS® Abutments for MIS Conical Connection Implant are endosseous dental implant abutments.

The proposed devices are compatible with:

a. MIS V3 conical connection narrow and standard dental implant diameters Ø3.3, 3.9, 4.3 and 5.0 mm (K163349)

b. MIS C1 narrow, standard and wide platform conical connection implant diameters Ø3.3, 3.75, 4.2, and 5.0 (K172505, K112162)

Refer to Table 5.1 for the implants the proposed ATLANTIS® Abutments for MIS Conical Connection Implant are compatible with.

Table 5.1 Implant systems which proposed ATLANTIS® Abutments for MIS Conical Connection Implant are compatible with.

Trade Name	**Abutment Platform Diameter**	**Implant Diameter**
Atlantis Abutment for MIS V3 NP	Ø2.765mm	V3: Ø3.30 mm
Atlantis Abutment for MIS C1 NP	Ø2.76mm	C1: Ø3.30 mm
Atlantis Abutment for MIS C1 & V3 SP	Ø3.16mm	C1: Ø3.75, 4.2 mm V3: Ø3.90, 4.3, 5.0 mm
Atlantis Abutment for MIS C1 WP	Ø4.01mm	C1: Ø5.0

The abutments are available in four (4) designs:

a. **ATLANTIS® Abutment** for MIS Conical Connection Implant,

b. **ATLANTIS® Crown Abutment** for MIS Conical Connection Implant,

c. **ATLANTIS® Conus Abutment** (Custom or Overdenture) for MIS Conical Connection Implant

d. **ATLANTIS® Healing Abutment** for MIS Conical Connection Implant

The materials composition of the proposed devices are described below in Table 5.2.

Table 5.2 ATLANTIS® Abutment for MIS Conical Connection Implant Materials

Abutment	**ATLANTIS® Abutment for MIS Conical Connection Implant**	**ATLANTIS® Crown Abutment for MIS Conical Connection Implant**	**ATLANTIS® Conus Abutment (Custom) for MIS Conical Connection Implant**	**ATLANTIS® Conus Abutment (Overdenture) for MIS Conical Connection Implant**	**ATLANTIS® Healing Abutment for MIS Conical Connection Implant**
Materials	Titanium, Gold-shaded Titanium (Gold-Hue)	Titanium	Titanium, Gold-shaded Titanium (Gold-Hue)	Titanium	Titanium, Gold-shaded Titanium (Gold-Hue)

The maximum abutment height is 15 mm above implant interface and the minimum abutment height is 4 mm above the trans-mucosal collar. The abutments are provided straight and up to 30° of angulation.

All proposed abutments are patient-specific abutments fabricated using CAD/CAM technology by Dentsply Sirona Implants. Each abutment is designed according to prescription instructions from the clinician to support a screw-retained, cement-retained or friction fit prosthesis.

The coronal portion of the ATLANTIS® Abutments for MIS Conical Connection Implant can be fabricated as a conventional abutment for prosthesis attachment (ATLANTIS® Abutment for MIS Conical Connection Implant or ATLANTIS® Conus Abutment for MIS Conical Connection Implant), fabricated as a single tooth final restoration onto which porcelain is added ATLANTIS® Crown Abutment for MIS Conical Connection Implant) or fabricated with a short core for soft tissue healing (ATLANTIS® Healing Abutment).

5. Indications for Use

The ATLANTIS® Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS® Abutment to the endosseous implant.

The ATLANTIS® Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS® Crown Abutment to the endosseous implant.

The ATLANTIS® Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS® Conus Abutment to the endosseous implant.

The ATLANTIS® Healing Abutment can be used with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The abutment screw is intended to secure the ATLANTIS® Healing Abutment to the endosseous implant.

ATLANTIS® Abutment is compatible with MIS Conical Connection implant from MIS Implant System.

ATLANTIS® products are compatible with the implants shown in the table below.

Implant manufacturer - MIS-IMPLANT TECHNOLOGIES INC

Trade Name	Abutment Platform Diameter	Implant Diameter
Atlantis Abutment for MIS V3 NP	Ø2.765mm	V3: Ø3.30 mm
Atlantis Abutment for MIS C1 NP	Ø2.76mm	C1: Ø3.30 mm
Atlantis Abutment for MIS C1 & V3 SP	Ø3.16mm	C1: Ø3.75,4.2 mm, V3: Ø3.90,4.3,5.0 mm
Atlantis Abutment for MIS C1 WP	Ø4.01mm	C1: Ø5.0 mm

6. Substantial Equivalence Discussion

ATLANTIS® Abutment for MIS Conical Connection Implant is a patient specific restorative device designed by Dentsply Sirona Implants technicians and manufactured by Dentsply Sirona Implants using CAD/CAM technology.

With the exception of the abutment to implant interface geometry, the design of the ATLANTIS® Abutment for MIS Conical Connection Implant, ATLANTIS® Conus Abutment for MIS Conical Connection Implant, and ATLANTIS® Crown Abutment for MIS Conical Connection Implant are identical to the design of the predicate ATLANTIS® Abutment for MIS Implant (K172225). Both the proposed ATLANTIS® Abutment for MIS Conical Connection Implants and the predicate device (K172225) are composed of the identical titanium alloy conforming to ASTM F136 (*Standard Specification for Wrought Titanium-6 Alumin-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*) and are both offered in a "Gold Hue" variants which feature a titanium nitride coating to produce a gold-shaded external surface. The difference in implant connection interface geometry is due to the compatibility requirement of the proposed devices with the specified MIS Conical Connection Implants (versus that of the predicate device (K172225) which feature implant interface geometry designed for compatibility with MIS Internal Hex Implants). Dynamic fatigue testing according to international standard ISO 14801 (*Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants*) has been conducted and is included in support of substantial equivalence with respect to the difference in implant interface geometry.

The abutment platform diameter range of the proposed devices is similar to that of the predicate device (K172225). Differences in abutment platform diameter do not impact substantial equivalence in that abutment platform diameter changes according to the corresponding platform connection. However, specifications, including abutment diameter, of the final, finished abutment are identical for all ATLANTIS® abutments.

The design of the ATLANTIS® Healing Abutment is similar to the design of the predicate, V3 Conical Connection Healing Caps (K163349). The differences in height above the margin do not affect substantial equivalence as the healing abutment is used only in the healing phase and does not carry any load. In the case of the subject ATLANTIS Healing Abutment, the healing cap diameter is the customized, patient-specific portion of the healing cap.

The design specifications of the final, finished patient-specific design of the proposed ATLANTIS® Abutment for MIS Conical Connections Implants are identical to those of the predicate ATLANTIS® Abutment for MIS Implant cleared under K172225. The final design of both the proposed and predicate (K172225) adhere to the same design limitations within the final patient-specific design, including: maximum abutment angulation of 30°, maximum abutment height of 15 mm above the implant interface, maximum abutment post height above the trans-mucosal collar of 4 mm, as well as, final abutment width of 3.3 mm to 6.5 mm.

The proposed devices have the identical intended use, are manufactured using the identical materials and processes, designed and manufactured in the identical facility, and are characterized by the identical fundamental product technology as the predicate device (K172225). The indications for use of the proposed device are similar to those of the predicate device (K172225) but differ in that they reference the proposed device's compatibility with the MIS Conical Connection Implants (while the predicate device (K172225) indications reference compatibility with MIS Internal Hex Implants). The proposed indications for use also include the indications for the ATLANTIS Healing Abutments intended as compatible with the MIS Conical Connection Implants in this premarket notification. Geometric compatibility analysis and bench testing have been included in support of substantial equivalence with respect to these differences in the proposed indications for use compared to the cleared indications for use of the predicate device (K172225).

Table 5.3 compares the proposed devices [ATLANTIS® Abutment, ATLANTIS® Crown Abutment, and ATLANTIS® Conus Abutment (Custom or Overdenture)]. Table 5.4 compares the proposed ATLANTIS® Healing Abutment with the reference device, K163349, V3 Conical Connection Healing Caps.

Table 5.3 – Substantial Equivalence Comparison Summary (ATLANTIS Abutments, ATLANTIS Conus Abutments, ATLANTIS Crown Abutments

ATLANTIS® Abutment for MIS Conical Connection Implant Proposed device	**ATLANTIS® Abutment for MIS Implant K172225 Predicate Device**
The **ATLANTIS® Abutment** is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS® Abutment to the endosseous implant. The **ATLANTIS® Crown Abutment** is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS® Crown Abutment to the endosseous implant. The **ATLANTIS® Conus Abutment** is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS® Conus Abutment to the endosseous implant. The **ATLANTIS® Healing Abutment** can be used with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The abutment screw is intended to secure the ATLANTIS® Healing Abutment to the endosseous implant. **ATLANTIS® Abutment** is compatible with MIS Conical Connection implant from MIS Implant System. **ATLANTIS®** products are compatible with the implants shown in the table below: Implant manufacturer : MIS IMPLANT TECHNOLOGIES LTD	The **ATLANTIS® Abutment** is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS® Abutment to the endosseous implant. The **ATLANTIS® Crown Abutment** is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS® Crown Abutment to the endosseous implant. The **ATLANTIS® Conus Abutment** is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS® Conus Abutment to the endosseous implant. **ATLANTIS® Abutment** for MIS implant is compatible with MIS implant from MIS Implant System. MIS short implants (6mm) are to be used only with straight abutments. ATLANTIS® products are compatible with the implants shown in the table below: Implant manufacturer : MIS IMPLANT TECHNOLOGIES LTD

Trade Name	Abutment Platform Diameter	Implant Diameter	Trade Name	Abutment Platform Diameter	Implant Diameter
Atlantis Abutment for MIS V3 NP	Ø2.765mm	V3: Ø3.30mm	MIS Implant M4 & SEVEN Narrow Platform	Ø3.30 mm	Ø3.30 mm
Atlantis Abutment for MIS C1 NP	Ø2.76mm	C1: Ø3.30mm			
Atlantis Abutment for MIS C1 & V3 SP	Ø3.16mm	C1: Ø3.75, 4.2 mm, V3: Ø3.90, 4.3, 5.0 mm	MIS Implant M4 & SEVEN Standard Platform	Ø3.75 and 4.2 mm	Ø3.75 and 4.2 mm
Atlantis Abutment for MIS C1 WP	Ø4.01mm	C1: Ø5.0 mm	MIS Implant M4 & SEVEN Wide Platform	Ø5.0 and 6.0 mm	Ø5.0 and 6.0 mm

Table 5.3 – Substantial Equivalence Comparison Summary (ATLANTIS Abutments, ATLANTIS Conus Abutments, ATLANTIS Crown Abutments (continued).		
	ATLANTIS® Abutment for MIS Conical Connection Implant Proposed device	**ATLANTIS® Abutment for MIS Implant K172225 Predicate Device**
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit
Restoration	Single or Multi-unit	Single or Multi-unit
Abutment platform diameter	Ø2.765, 2.76, 3.16, 4.01 mm	Ø 3.3, 3.75, 4.2, 5.0, 6.0 mm
Abutment Angle	Straight, up to 30º	Straight, up to 30º
Max. Abutment Height	15 mm	15 mm
Min. Abutment Post Height	4 mm	4 mm
Design type	Patient specific design	Patient specific design
Implant Connection	Conical Connection	Internal hex connection
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue) [conforming to ASTM F136]	- Titanium alloy, Gold Shaded Titanium (Gold Hue), [conforming to ASTM F136] - Zirconia
Material: Screw	Titanium alloy [conforming to ASTM F136]	Titanium alloy [conforming to ASTM F136]

Table 5.4-Difference and Similarities of proposed, predicate and reference devices (Healing Abutments)		
Trade Name	**ATLANTIS® Abutment for MIS Conical Connection Implant Healing Abutment Proposed Device**	**V3 Conical Connection Healing Caps K163349 Reference Device**
Material(s)	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium 6Al-4V ELI per ASTM F136
Interface Diameter	Ø2.76, 2.765, 3.16, 4.01 mm	Cover screws: 2.77,3.15 mm Healing caps: 3.3,3.9,4.0,4.8,5.8 mm
Gingival height – healing caps	0.5mm to 4mm (above the margin)	2,3,4,5,6,8
Surface Treatment/	N/A	Polished and anodized after machined
Connection Type	Conical Connection	Conical connection without indexes
Platform	NP/SP/WP	NP/SP
Sterilization Method	Steam sterilized by end user	Radiation

7. Non-Clinical Performance Data

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

   - Fatigue testing was conducted according to ISO 14801: *Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants*. Fatigue test results were compared to the predicate and reference devices.
   - Geometric compatibility analysis was conducted on OEM implant bodies, OEM abutments, and OEM screws to support the dimensional compatibility of the ATLANTIS® Abutment for MIS Conical Connection Implant with the MIS V3 implants (Narrow: Ø3.3mm and Standard: Ø3.9, 4.3, 5.0mm) and MIS C1 implants (Narrow Ø3.3mm, Standard: Ø3.75, 4.2mm and Wide: Ø5.0, 6.0 mm).
   - Sterilization validation of the proposed device is referenced by equivalency to the sterilization validation of predicate (K172225). Predicate device was validated 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.
   - The material composition and manufacturing processing methods of the proposed ATLANTIS® Abutment for MIS Conical Connection Implant are identical to the predicate device, ATLANTIS® Abutment for MIS Implant (K172225). Therefore, no additional biocompatibility data is included to support substantial equivalence.

8. Clinical Performance Data

   No human clinical data was included in this premarket notification to support substantial equivalence of the proposed modification to predicate device ATLANTIS® Abutment for MIS Implant (K172225).

9. Conclusion Regarding Substantial Equivalence

   The proposed ATLANTIS® Abutments for MIS Conical Connection Implant are endosseous dental implant abutments which are intended to support a prosthetic device in partially or completely edentulous patients. The proposed ATLANTIS® Abutment for MIS Conical Connection Implant has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicate device ATLANTIS® Abutment for MIS Implant (K172225). The proposed device fatigue testing results are substantially equivalent to those of the ATLANTIS® Abutment for HIOSSEN ET Implant (K160626) and therefore this predicate was included as a reference device. The proposed healing abutments are also technologically substantially equivalent to those of the V3 Conical Connection Healing Caps (K163349) and therefore this predicate was also included as a reference device.

   In addition, the proposed ATLANTIS® Abutments are compatible with the following implant systems: MIS C1 Narrow Platform Conical Connection Implant System (K172505), MIS C1 Standard and Wide Platform Conical Connection Abutment (K112162), MIS V3 Conical Connection Dental Implant System (K163349). Non-clinical bench testing has been conducted and are included in this premarket notification to demonstrate the performance of the proposed ATLANTIS® Abutments for MIS Conical Connection Implant in support of substantial equivalence. 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 ATLANTIS® Abutments for MIS Conical Connection Implant to the predicate devices.