November 30, 2017

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

Re: K172225
Trade/Device Name: ATLANTIS® Abutment for MIS Implant
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 31, 2017
Received: September 1, 2017

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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172225

Device Name
ATLANTIS® Abutment for MIS Implant

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.

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 INC

Trade Name	Abutment Platform Diameter	Implant Diameter
MIS Implant M4 & SEVEN Narrow Platform	Ø3.30 mm	Ø3.30 mm
MIS Implant M4 & SEVEN Standard Platform	Ø3.75 and 4.2 mm	Ø3.75 and 4.2 mm
MIS Implant M4 & SEVEN Wide Platform	Ø5.0 and 6.0 mm	Ø5.0 and 6.0 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.

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

SECTION 5. 510(k) SUMMARY
K172225
ATLANTIS® Abutment for MIS Implant

1. Submitter Information**:**

Dentsply Sirona
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: November 30, 2017

2. Device Name:

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

3. Predicate Device:

Predicate Device Name	510(k)	Company Name
ATLANTIS® Abutment for HIOSSEN ET Implant	K160626	DENTSPLY IMPLANTS
MIS Dental Implant System (Reference Predicate Device)	K040807	MIS-IMPLANT TECHNOLOGIES INC
MIS Short Implants (Reference Predicate Device)	K103089	MIS-IMPLANT TECHNOLOGIES INC

4. Description of Device:

The proposed *ATLANTIS® Abutment for MIS Implant* is an endosseous dental implant abutment. The subject device is provided for implant diameter (Ø3.3, 3.75, 4.2, 5.0 and 6.0 mm) and three designs: ATLANTIS® Abutment for MIS Implant, ATLANTIS® Crown Abutment for MIS Implant and ATLANTIS® Conus Abutment for MIS Implant, see table 5-1. All are patient-specific abutments fabricated using CAD/CAM technology at Dentsply Implant manufacturing sites. Each abutment is designed according to prescription instructions from the clinician to support a screw-retained, cement-retained or friction fit prosthesis.

Table 5-1: Compatibility table (The ATLANTIS® Abutment Titanium, Zirconia and Gold-shaded are compatible with MIS implant interface (Ø3.3, 3.75, 4.2, 5.0 and 6.0 mm)

Implant Manufacturer	Interface	ATLANTIS® Abutment for MIS Implant	ATLANTIS® Crown Abutment for MIS Implant	ATLANTIS® Conus Abutment for MIS Implant (Custom)	ATLANTIS® Conus Abutment for MIS implant (Overdenture)
MIS-IMPLANT TECHNOLOGIES INC	MIS M4 & SEVEN Implant System (MIS implant) (Ø3.3, 3.75, 4.2, 5.0 and 6.0 mm)	Titanium, Zirconia, Gold-shaded Titanium (Gold-Hue)	Titanium, Zirconia	Titanium, Gold-shaded Titanium (Gold-Hue)	Titanium

The coronal portion of the ATLANTIS® Abutment can be fabricated as a conventional abutment for prosthesis attachment (ATLANTIS® Abutment or ATLANTIS® Conus Abutment) or fabricated as a single tooth final restoration onto which porcelain is added (ATLANTIS® Crown Abutment). The ATLANTIS® abutment interface is compatible with the MIS implants from the MIS Implant System (K040807) and MIS implants from MIS Short Implants (K103089).

The MIS M4 & SEVEN implant interface has an internal hex connection and provided for implant platform diameter Narrow (3.30 mm), Standard (3.75 and 4.20 mm) and Wide (5.0 and 6.0 mm). The abutment height ranges from 3.3 to 13 mm, the maximum abutment height is 15 mm above implant interface and the minimum abutment height is 4 mm above the trans-mucosal collar. The abutment is provided straight and up to 30° of angulation.

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.

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 INC

Trade Name	Abutment Platform Diameter	Implant Diameter
MIS Implant M4 & SEVEN Narrow Platform	Ø3.30 mm	Ø3.30 mm
MIS Implant M4 & SEVEN Standard Platform	Ø3.75 and 4.2 mm	Ø3.75 and 4.2 mm
MIS Implant M4 & SEVEN Wide Platform	Ø5.0 and 6.0 mm	Ø5.0 and 6.0 mm

6. Substantial Equivalence:

Technological Characteristics

ATLANTIS® Abutment for MIS implant is a patient specific restorative device designed under the control of Dentsply Implants and manufactured by Dentsply Implants using CAD/CAM technology.

Table 5-2 and 5-3 below summarizes the differences and similarities of the subject and predicate devices.

Table 5-2: Indications for use for the proposed and the predicate devices

ATLANTIS® Abutment for MIS Implant (Proposed Device)	ATLANTIS® Abutment for HIOSSEN ET Implant (K160626) (Primary Predicate)	MIS Dental Implant System (K040807) (Reference Predicate)	MIS Short Implants (K103089) (Reference Predicate)	Summary of differences in the 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	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	The **MIS Dental Implant System** is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.	**MIS Dental Implants** 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 a patient's chewing 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. MIS short implants are to be used only with straight abutments.	The indications for use of the proposed device are similar to the indications for use of the primary predicate device. The difference is that the indications for use of the primary predicate device are for Hiossen ET implant system. The indications for use of the reference predicate device cover the entire dental system. The indications for use are similar. The difference between the proposed device and the reference predicate device is that the prosthesis, in addition to screw-retained restoration or cement retained restoration, can be attachment-retained (friction fit) to the proposed device.

Table 5-2: Indications for use for the proposed and the predicate devices

<table>
<tr><th>ATLANTIS® Abutment for MIS implant
(Proposed Device)</th><th>ATLANTIS® Abutment for HIOSSEN ET Implant (K160626)
(Primary Predicate)</th><th>MIS Dental Implant System (K040807)
(Reference Predicate)</th><th>MIS Short Implants (K103089)
(Reference Predicate)</th><th>Summary of differences in the indications for use</th></tr>
<tr><td colspan="3">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 ALTLANTIS® 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, INC</td><td colspan="3">friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS® Conus Abutment to the endosseous implant.

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

Implant Manufacturer:
HIOSSEN INC</td><td></td><td></td><td></td></tr>
<tr><td>Trade Name</td><td>Abutment Platform Diameter</td><td>Implant Diameter</td><td>Trade Name</td><td>Abutment Platform Diameter</td><td>Implant Diameter</td><td></td><td></td><td></td></tr>
<tr><td>MIS Implant M4 & SEVEN Narrow Platform</td><td>Ø3.30 mm</td><td>Ø3.30 mm</td><td>HIOSSEN ET III SA Fixture Mini</td><td>Ø3.5mm</td><td>Ø3.5mm</td><td></td><td></td><td></td></tr>
<tr><td>MIS Implant M4 & SEVEN Standard Platform</td><td>Ø3.75 and 4.2 mm</td><td>Ø3.75 and 4.2 mm</td><td rowspan="2">HIOSSEN ET III SA Fixture Regular</td><td rowspan="2">Ø4.0, 4.5, 5.0, 6.0,7.0 mm</td><td rowspan="2">Ø4.0, 4.5, 5.0, 6.0, 7.0 mm</td><td></td><td></td><td></td></tr>
<tr><td>MIS Implant M4 & SEVEN Wide Platform</td><td>Ø5.0 and 6.0 mm</td><td>Ø5.0 and 6.0 mm</td><td></td><td></td><td></td></tr>
</table>

Table 5-3: Similarities and differences between the proposed and the predicate devices					
Element	**Proposed Device ATLANTIS® Abutment for MIS Implant**	**Primary Predicate Device ATLANTIS® Abutment for HIOSSEN ET Implant**	**Reference Predicate Device MIS Dental Implant System**	**Reference Predicate Device MIS Short Implants**	**Summary of differences**
510(k)	To be assigned	K160626	K040807	K103089	-
Prosthesis Attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained	Screw-retained Cement-retained	No difference between the proposed and the primary predicate device. The reference device does not indicate friction fit.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	No difference
Abutment Platform Diameter	3.3, 3.75, 4.2, 5.0, 6.0	3.5, 4.0, 4.5, 5.0, 6.0, 7.0	3.3, 3.75, 4.2, 5.0, 6.0	4.2, 5.0, 6.0	The proposed device is designed to fit the MIS interface. Therefore, no difference between the proposed device and the reference predicate device.

Table 5-3: Similarities and differences between the proposed and the predicate devices					
Element	**Proposed Device ATLANTIS® Abutment for MIS Implant**	**Primary Predicate Device ATLANTIS® Abutment for HIOSSEN ET Implant**	**Reference Predicate Device MIS Dental Implant System**	**Reference Predicate Device MIS Short Implants**	**Summary of differences**

Abutment angle	Straight, up to 30°	Straight, up to 30°	Straight, up to 30°	Straight	No difference
Connection	Internal hex connection	Internal hex connection	Internal hex connection	Internal hex connection	There is no difference between the proposed device and the reference predicate device.
Material Implant	NA	NA	Titanium Alloy Ti 6Al 4V ELI	Titanium Alloy	The proposed device is an abutment.
Material: Abutment	Titanium alloy, Zirconia	Titanium alloy, Zirconia	Titanium alloy	Titanium Alloy	No difference
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy	No difference

7. Non-Clinical Performance Data

Non-clinical test data and analyses are included to support substantial equivalence:

- Static and dynamic compression-bending testing conducted according to ISO 14801: *Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants.*

- Geometric analyses conducted on implant bodies, abutments, and screws to support the dimensional compatibility of the ATLANTIS® Abutment for MIS Implant with the MIS Implant Technologies, Inc., Narrow (Ø3.30 mm), Standard (Ø3.75 and 4.2 mm), and Wide (Ø5.0 and 6.0 mm), M4 and SEVEN implant platforms.

- Sterilization parameters which have been 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,* and ISO 20857: *Sterilization of health care products -- Dry heat -- Requirements for the development, validation and routine control of a sterilization process for medical devices* are included and are as referenced in the predicate device (K160626).

Biocompatibility

The material composition and manufacturing processing methods of the subject ATLANTIS® Abutment for MIS Implant are identical to the predicate device, ATLANTIS® Abutment for Hiossen ET Implant (K160626). Therefore, no additional biocompatibility data is included to support substantial equivalence.

8. Conclusion Regarding Substantial Equivalence

The ATLANTIS® Abutment for MIS Implant is an endosseous dental implant abutment which is intended to support a prosthetic device in a partially or completely edentulous patient. The ATLANTIS® Abutment for MIS Implant has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicates, ATLANTIS® Abutment for HIOSSEN ET Implant (K160626), MIS Dental Implant System (K040807) and MIS Short Implants (K103089). Test data to verify the performance of the ATLANTIS® Abutment for MIS Implant has been provided with mechanical testing. The results of the test studies and dimensional compatibility analyses, combined with the design, and intended use comparison with the predicate devices, support substantial equivalence.