DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 29, 2016

Dentsply Sirona
Ms. Helen Lewis
Director, Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

Re: K160626
Trade/Device Name: ATLANTIS™ Abutment for HIOSSEN ET implant
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: II
Product Code: NHA
Dated: July 21, 2016
Received: July 22, 2016

Dear Ms. Lewis:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160626

Device Name
ATLANTIS™ Abutment for HIOSSEN ET 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™ products are compatible with the implants shown in the table below.

Implant Manufacturer - HIOSSEN INC

Trade Name	Abutment Platform Diameter	Implant Diameter
HIOSSEN ET III SA Fixture Mini	Ø3,5mm	Ø3,5mm
HIOSSEN ET III SA Fixture Regular	Ø4.0, 4.5, 5.0, 6.0, 7.0 mm	Ø4.0, 4.5, 5.0, 6.0, 7.0 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
221 West Philadelphia Street
Suite 60
York, PA 17404

Dentsply Sirona

SECTION 5. 510(k) SUMMARY
for
ATLANTIS™ Abutment for HIOSSEN ET implant

1. Submitter Information:

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

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343

Date Prepared: August 17, 2016

2. Device Name:

- Proprietary Name: ATLANTIS™ Abutments for HIOSSEN ET 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
Osseospeed™ Profile EV (Primary Predicate Device)	K130999	DENTSPLY IMPLANTS MANUFACTURING GMBH
HIOSSEN Implant System (Reference Predicate Device)	K140934	HIOSSEN INC

4. Description of Device:

The proposed *ATLANTIS™ Abutment for HIOSSEN ET* implant is an endosseous dental implant abutment. The subject device is provided for implant diameter (Ø3.5, 4.0, 4.5, 5.0, 6.0 and 7.0 mm) and three designs: ATLANTIS™ Abutment for HIOSSEN ET implant, ATLANTIS™ Crown Abutment for HIOSSEN ET implant and ATLANTIS™ Conus Abutment for HIOSSEN ET implant, see table 5-1. All are patient-specific abutments fabricated using CAD/CAM technology at DENTSPLY Implant sites. Each abutment is designed according to prescription instructions from the clinician to support a screw-retained, cement-retained or friction fit prosthesis.

SECTION 5. 510(k) SUMMARY (continued)

Table 5-1: Compatibility table (The ATLANTIS Abutment Titanium, Zirconia and Gold-shaded are compatible with HIOSSEN ET implant interface (Ø3.5, 4.0, 4.5, 5.0, 6.0, 7.0 mm)

Implant Manufacturer	Interface	ATLANTIS™ Abutment for HIOSSEN ET implant	ATLANTIS™ Crown Abutment for HIOSSEN ET implant	ATLANTIS ™ Conus Abutment for HIOSSEN ET implant (Custom)	ATLANTIS™ Conus Abutment HIOSSEN ET implant (Overdenture)
HIOSSEN INC	HIOSSEN Implant System (HIOSSEN ET implant) (Ø3.5, 4.0, 4.5, 5.0, 6.0, 7.0 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 HIOSSEN ET implants from the HIOSSEN Implant System (K140934).

The HIOSSEN ET implant interface is a slight conical (11°) internal hex connection and provided for implant platform diameter Mini (3.5 mm), and Regular (4.0, 4.5, 5.0, 6.0 and 7.0 mm). The abutment diameter 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 transmucosal 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.

SECTION 5. 510(k) SUMMARY (continued)

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™ products are compatible with the implants shown in the table below.

Implant Manufacturer	Trade Name	Abutment Platform Diameter	Implant Diameter
HIOSSEN INC	HIOSSEN ET III SA Fixture Mini	Ø3,5mm	Ø3,5mm
	HIOSSEN ET III SA Fixture Regular	Ø4.0, 4.5, 5.0, 6.0, 7.0 mm	Ø4.0, 4.5, 5.0, 6.0, 7.0 mm

6. Substantial Equivalence:

Technological Characteristics:
ATLANTIS™ Abutment for HIOSSEN ET 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

<table>
<tr><th>ATLANTIS™ Abutment for HIOSSEN ET implant (Proposed Device)</th><th>OsseoSpeed Profile EV (K130999) (Primary Predicate)</th><th>HIOSSEN Implant System (K140934) (Reference Predicate)</th><th>Summary of differences in the indications for use</th></tr>
<tr>
<td>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™ products are compatible with the implants shown in the table below.

<table>
<tr><th>Implant Manufacturer</th><th>Trade Name</th><th>Abutment Platform Diameter</th><th>Implant Diameter</th></tr>
<tr><td rowspan="2">HIOSSEN INC</td><td>HIOSSEN ET III SA Fixture Mini</td><td>Ø3,5mm</td><td>Ø3,5mm</td></tr>
<tr><td>HIOSSEN ET III SA Fixture Regular</td><td>Ø4.0, 4.5, 5.0, 6.0, 7.0 mm</td><td>Ø4.0, 4.5, 5.0, 6.0, 7.0 mm</td></tr>
</table>
</td>
<td>Implants:
The ASTRA TECH Implant System – OsseoSpeed Profile EV implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:
• Replacing missing teeth in single or multiple unit applications in the mandible or maxilla.
• Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge
• Especially indicated for us in soft bone applications where implants with other implant surface treatment may be less effective
• Immediate and early loading for all indications
• Together with immediate loading protocol in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate
• Only together with Profile EV components, Implant Driver Profile EV, Radiographic Implant Guides Profile EV and non-Indexed prosthetic components

Abutments:
ASTRA TECH Implant System™-OsseoSpeed EV abutments are intended to be used in conjunction with ASTRA TECH Implant System™-OsseoSpeed EV in fully edentulous or partially edentulous maxillary and/or mandibular arches.</td>
<td>The HIOSSEN Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. ETIII SA Ultra-Wide Fixture is intended to be used in the molar region.</td>
<td>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 primary predicate device also includes the indications for use of the implants, which is not the subject of this submission.

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 (by friction fit) to the proposed device.</td>
</tr>
</table>

ATLANTIS™ Abutment for HIOSSEN ET implant (Proposed Device)	OsseoSpeed Profile EV (K130999) (Primary Predicate)	HIOSSEN Implant System (K140934) (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 prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the 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 partially or completely edentulous patients. The prosthesis is screw retained. The abutment screw is intended to secure the ATLANTIS™ 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 Abutment to the endosseous implant. ATLANTIS™ Abutment, ATLANTIS™ Crown Abutment and ATLANTIS™ Conus Abutment are compatible with ASTRA TECH Implant System Profile EV		

Table 5-3: Similarities and differences between the proposed and the predicate devices

Element	**Proposed Device** **ATLANTIS™ Abutment for HIOSSEN ET implants**	**Primary Predicate Device** **OsseoSpeed Profile EV**	**Reference Predicate Device** **HIOSSEN Implant System**	**Summary of differences**
510(k)	To be assigned	*K130999*	*K140934*	-
Prosthesis Attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	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	No difference.
Abutment Platform Diameter	3.5, 4.0, 4.5, 5.0, 6.0, 7.0	3.0, 4.2, 4.8	3.5, 4.0, 4.5, 5.0, 6.0, 7.0	The proposed device is designed to fit the HIOSSEN ET interface. Therefore, no difference between the proposed device and the reference predicate device.
Abutment angle	Straight, up to 30°	Straight, up to 30°	Straight, up to 30°	No difference.
Connection	Internal hex connection	Internal conical connection	Internal hex connection	There is no difference between the proposed device and the reference predicate device.
Material Implant	NA	Titanium	Titanium	The proposed device is an abutment.
Material: Abutment	Titanium alloy, Zirconia	Titanium alloy, Zirconia	Titanium alloy, Zirconia	No difference.
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	No difference.

Biocompatibility

The results of biocompatibility testing conducted for the predicate device, OsseoSpeed Profile EV (K130999), are valid because the material composition of the proposed device is similar to the ATLANTIS™ Abutments covered by the predicate device, OsseoSpeed Profile EV (K130999). Therefore, no additional biocompatibility testing has been conducted.

Sterility

The sterility testing conducted for the predicate device, OsseoSpeed Profile EV (K130999), was conducted with the same materials and same sterilization cycle. Therefore, no additional sterility testing was required for the proposed device, ATLANTIS™ Abutment for HIOSSEN ET implant.

7. Non-Clinical Performance Data

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence includes mechanical design analysis, dimensional analysis, and static and dynamic compression-bending testing according to ISO 14801 *Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants.*

Compatibility analysis shows that the ATLANTIS™ Abutment for HIOSSEN ET implant is compatible with the Mini (3.5 mm) and Regular (4.0, 4.5, 5.0, 6.0 and 7.0 mm) HIOSSEN ET implants. Mechanical testing results show that the ATLANTIS™ Abutment for HIOSSEN ET implant has sufficient strength for its intended use.

8. Conclusion Regarding Substantial Equivalence

The ATLANTIS™ Abutment for HIOSSEN ET 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 HIOSSEN ET implant has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicates, Osseospeed™ Profile EV (K130999) and HIOSSEN Implant System (K140934). Test data to verify the performance of the ATLANTIS™ Abutment for HIOSSEN ET implant has been provided including: mechanical testing and compatibility analysis. The results of this testing, combined with the design, and intended use comparison with the predicate devices, support substantial equivalence.