DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 29, 2016

DENTSPLY International Inc.
Ms. Helen Lewis
Director Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17401

Re: K152247
Trade/Device Name: ATLANTIS™ Crown
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: December 16, 2015
Received: December 22, 2015

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 yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): k152247

Device Name: ATLANTIS™ Crown

Indications for Use:

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

Prescription Use X	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY
for
ATLANTIS™ Crown

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
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York, PA 17401
(800) 877-0020
Fax (717) 849-4343
www.dentsply.com

1. Submitter Information:

DENTSPLY International, Inc.
Susquehanna Commerce Center
221 West Philadelphia Street, Ste. 60
York, PA 17401

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

Date Prepared: 04 August 2015

2. Device Name:

- Proprietary Name: ATLANTIS™ Crown
- classification Name: Porcelain powder for clinical use
- CFR Number: 21 CFR 872.6600
- Device Class: Class II
- Product Code: EIH

3. Predicate Device:

Primary Predicate: Cercon®ht, K112152 (DENTSPLY International Inc.)
Reference Predicate: ATLANTIS™ Crown Abutment in Zirconia, K110356 (DENTSPLY Implants, formerly ASTRA TECH Inc.)

The ATLANTIS™ Crown Abutment in Zirconia, (K110356) has been chosen as reference predicate regarding biocompatibility since the material and CAD/CAM milling process is identical to the proposed device.

4. Description of Device:

The ATLANTIS™ Crown is a patient-specific dental prosthetic component intended for use with an ATLANTIS™ Abutment, abutment screw, and an endosseous implant to support a single-tooth prosthetic restoration. The ATLANTIS™ Crown is made of yttria stabilized zirconia powder (Y-TZP) and fabricated according to the clinician's prescription using CAD/CAM technology. The crown can be delivered as a full contour crown or as a cut-back substructure onto which porcelain will be added by the customer. The ATLANTIS™ Crown is finally cemented to the ATLANTIS™ Abutment.

5. Indications for Use:

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

6. Substantial Equivalence:

Comparison of the Technological Characteristics:

	Proposed Device	**Primary Predicate Device**	**Reference Predicate Device**
	ATLANTIS™ Crown	Cercon® ht (K112152)	ATLANTIS™ Crown Abutment in Zirconia (K110356)
Indications for use	The ATLANTIS™ Crown is intended for use with an ATLANTIS™ Abutment and an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. .	Cercon® ht is indicated in the anterior and posterior segments for: * crowns * telescopic primary crowns * multi-unit bridges (with no more than two pontics between abutment crowns) Cercon® ht can be used as a substructure (framework) which is then veneered with a dental veneering ceramic or can be used for full-contour application (without veneering) as well. In the case of telescopic primary crowns the substructure is not veneered.	The Atlantis Crown Abutment in Zirconia 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 prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant. This device is compatible with the following manufacturers' implant systems: Astra - Microthread ST 3.5mm, 4.0mm, 4.5mm and 5.0mm. Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments on small diameter implants are intended for the anterior region of the mouth only.
Design	Provided to the customer as patient-specific full contour crown or cut-back substructure.	Provided as blank to the dental laboratory to create a patient-specific full contour crown or substructure	Provided as a patient-specific abutment, available in the diameters: 3.5 mm, 4.0 mm, 4.5 mm, 5.0 mm
Manufacturing method	1. pre-sintered blanks 2. milling of crown by DENTSPLY Implants 3. final sintering by DENSPLY Implants	1. pre-sintered blanks 2. machining of crown by dental laboratory 3. final sintering by dental laboratory	1. pre-sintered blanks 2. milling of abutment by DENTSPLY Implants 3. final sintering by DENTSPLY Implants
Material	Y-TZP	Y-TZP	Y-TZP

7. Non-Clinical Performance Data.

Flexural strength testing were conducted on the Zirconia material used for the ATLANTIS™ Crown according to the standards ISO 14704 and ASTM C1161. The results showed that the requirements of the standard ISO 6872 *Dentistry Ceramic Materials* were fulfilled. Fracture toughness, chemical solubility, radioactivity concentration and coefficient of thermal expansion were tested and completed according to the requirements specified in ISO 6872.

The material used for the ATLANTIS™ Crown and the manufacturing process is the same as used for the predicate device ATLANTIS™ Crown Abutment in Zirconia, K110356. Therefore no additional biocompatibility testing has been performed.

8. Conclusion Regarding Substantial Equivalence

The ATLANTIS™ Crown is a patient-specific restorative device which is intended to be used with an ATLANTIS™ Abutment and an endosseous implant. The ATLANTIS™ Crown and the primary predicate, Cercon ht (K112152), can be delivered as a full contour crown or as a cut-back substructure onto which porcelain will be added by the customer. Thus, it can be concluded that the ATLANTIS™ Crown has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the primary predicate device Cercon® ht (K112152).

Thus, it can be concluded that the proposed ATLANTIS™ Crown is substantially equivalent to the predicate devices.