



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

February 19, 2016

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

Re: K151439

Trade/Device Name: Atlantis™ ISUS  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: II  
Product Code: NHA  
Dated: January 20, 2016  
Received: January 21, 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" (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.

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,

 Tina Kiang -  
S

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

## SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number: K151439

Device Name: ATLANTIS™ ISUS

### ATLANTIS™ ISUS:

ATLANTIS™ ISUS implant suprastructures are indicated for attachment to dental implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

ATLANTIS™ ISUS implant suprastructures are intended for attachment to a minimum of two (2) implants and are indicated for compatibility with the following implant and abutment systems:

### Implants:

- 3i Internal Connection: D3.4, D4.1, D5, D6
- Friadent XiVE S: D3.0, D3.4, D3.8, D4.5, D5.5
- Nobel Biocare Active Internal: NP (3.5mm), RP (4.3mm, 5.0mm)
- Nobel Biocare Replace Select: NP (3.5mm), RP (4.3mm), WP (5.0mm) and Replace Select 6.0mm
- Straumann Bone Level: NC (3.3mm), RC (4.1mm, 4.8mm)
- Straumann NN (3.5mm), RN (4.8mm), WN (6.0mm)
- Zimmer Screw Vent: D3.5, D4.5, D5.7

### Abutments:

- 3i Low Profile Abutment
- ANKYLOS Balance Base Abutment D5.5 and Narrow Abutment D4.2
- ASTRA TECH 20° and 45° UniAbutment
- Astra Tech UniAbutment EV 3.6
- Friadent XiVE MP D3.8, D4.5, D5.5
- Friadent XiVE TG D3.8, D4.5, D5.5
- Nobel Biocare Multi-Unit Abutment RP: 4.0 mm
- Straumann Bone Level Angled Abutment: 4.0 mm
- Straumann Bone Level: Multi-Base Abutment D3.5, D4.5
- Straumann RN (4.8 mm), WN (6.5 mm)
- Zimmer Tapered Abutment: 4.5 mm

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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™ ISUS**

**DENTSPLY International**  
World Headquarters  
Susquehanna Commerce Center  
221 West Philadelphia Street  
Suite 60W  
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, Suite 60W  
York, PA 17401

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

Date Prepared: 28 May 2015

2. Device Name:

- Proprietary Name: ATLANTIS™ ISUS
- Classification Name: Endosseous dental implant abutment
- CFR Section: 21 CFR 872.3630
- Device Class: Class II
- Product Code: NHA

3. Predicate Devices:

The subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices. The primary predicate device is K122424.

Predicate Device Name	510(k)	Company Name
ISUS Implant Suprastructures (Primary Predicate Device)	K122424	DENTSPLY International Inc.
Procera Implant Bridge Overdenture	K090069	Nobel Biocare USA, LLC
ANKYLOS SynCone Abutment 5°	K131644	DENTSPLY International Inc.
NobelProcera Angulated Screw Channel Abutment Replace	K133377	Nobel Biocare USA, LLC

4. Description of Device:

ATLANTIS™ ISUS is a custom restorative device that is intended to be attached to dental implants or abutments to facilitate prosthetic restoration in the treatment of partially and totally edentulous patients. The design of the subject device is derived from patient dental models and completed by DENTSPLY technicians using computer-assisted design (CAD) according to the clinician's prescription. The final CAD design of ATLANTIS™ ISUS is fabricated using computer-assisted manufacturing (CAM) to produce a custom patient specific device.

ATLANTIS™ ISUS is available in four design types.

1. Bar – Intended as a fixed supporting structure for a removable dental prosthesis.
2. Bridge – Intended for direct veneering using dental ceramics or resin composites resulting in a fixed, screw-retained prosthesis.
3. Hybrid – Intended as a fixed denture framework.
4. 2 in 1 – Intended as a fixed supporting structure for a removable dental prosthesis in combination with a hybrid denture framework retained by friction fit. The primary structure is a non-standard bar configuration. The secondary structure is a bridge or hybrid denture restoration with a tapered friction fit connection rather than a screw-retained connection.

Angulated Screw Access (Screws):

The purpose of Angulated Screw Access (ASA) is to place the position of the screw-channel opening in a non-visual area by changing the angulation of the screw-channel. ASA allows the prosthetic screw access channel to be angled up to 30° off the implant/abutment axis for optimal esthetics and function. ASA screws have a hexalobular driving feature in the screw head allowing the hexalobular screwdriver to engage the screw head at a 30° angle. ASA screws are available for all compatible implant systems. (See Indications for Use Statement for compatible implant systems.)

#### 5. Indications for Use:

ATLANTIS™ ISUS:

ATLANTIS™ ISUS implant suprastructures are indicated for attachment to dental implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

ATLANTIS™ ISUS implant suprastructures are intended for attachment to a minimum of two (2) implants and are indicated for compatibility with the following implant and abutment systems:

Implants:

- 3i Internal Connection: D3.4, D4.1, D5, D6
- Friadent XiVE S: D3.0, D3.4, D3.8, D4.5, D5.5
- Nobel Biocare Active Internal: NP (3.5mm), RP (4.3mm, 5.0mm)
- Nobel Biocare Replace Select: NP (3.5mm), RP (4.3mm), WP (5.0mm) and Replace Select 6.0mm
- Straumann Bone Level: NC (3.3mm), RC (4.1mm, 4.8mm)
- Straumann NN (3.5mm), RN (4.8mm), WN (6.0mm)
- Zimmer Screw Vent: D3.5, D4.5, D5.7

Abutments:

- 3i Low Profile Abutment
- ANKYLOS Balance Base Abutment D5.5 and Narrow Abutment D4.2
- ASTRA TECH 20° and 45° UniAbutment
- Astra Tech UniAbutment EV 3.6
- Friadent XiVE MP D3.8, D4.5, D5.5
- Friadent XiVE TG D3.8, D4.5, D5.5
- Nobel Biocare Multi-Unit Abutment RP: 4.0 mm
- Straumann Bone Level Angled Abutment: 4.0 mm
- Straumann Bone Level: Multi-Base Abutment D3.5, D4.5
- Straumann RN (4.8 mm), WN (6.5 mm)
- Zimmer Tapered Abutment: 4.5 mm

6. Substantial Equivalence:

Technological Characteristics.

ATLANTIS™ ISUS is a custom restorative device with the following technological characteristics equivalent to the predicate devices:

- Fabricated using computer-assisted design (CAD) according to the clinician’s prescription.
- Milled using computer-assisted manufacturing (CAM).
- Fabricated from homogenous, single-block raw material (CPTi or CoCr alloy).

Table 6.1 below describes the differences and similarities of the subject and predicate devices.

<b>Table 6.1</b>		Primary predicate	Reference device	Reference device	Reference device
	<b>Subject Device</b>	<b>Predicate Devices</b>			
	DENTSPLY International Inc.  Atlantis™ ISUS	DENTSPLY International Inc.  ISUS Implant Suprastructures  K122424	Nobel Biocare USA, LLC  Procera Implant Bridge Overdenture  K090069	DENTSPLY International Inc.  ANKYLOS SynCone Abutment 5°  K131644	Nobel Biocare USA, LLC  NobelProcera Angulated Screw Channel Abutment Replace K133377
<b>Indications for Use</b>	ATLANTIS™ ISUS implant suprastructures are indicated for attachment to dental implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.  ATLANTIS™ ISUS	The ISUS Implant Suprastructures are indicated for attachment to dental implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function. The ISUS Implant Suprastructures are intended for	The Procera Implant Bridge Overdenture is indicated for use as an overdenture bar that attaches to implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.	Anchorage of dentures retained by taper friction and supported by ANKYLOS implants.  Immediate loading of an implant supported prosthesis in an edentulous mandible supported by 4 ANKYLOS implants of at least 11mm in length and placed	The NobelProcera Angulated Screw Channel Abutment Replace are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

<b>Table 6.1</b>	Primary predicate	Reference device	Reference device	Reference device	Reference device
	<b>Subject Device</b>	<b>Predicate Devices</b>			
	DENTSPLY International Inc.  Atlantis™ ISUS	DENTSPLY International Inc.  ISUS Implant Suprastructures  K122424	Nobel Biocare USA, LLC  Procera Implant Bridge Overdenture  K090069	DENTSPLY International Inc.  ANKYLOS SynCone Abutment 5°  K131644	Nobel Biocare USA, LLC  NobelProcera Angulated Screw Channel Abutment Replace K133377
	<p>implant suprastructures are intended for attachment to a minimum of two (2) implants and are indicated for compatibility with the following implant and abutment systems:</p> <p>Implants:</p> <ul style="list-style-type: none"> <li>• 3i Internal Connection: D3.4, D4.1, D5, D6</li> <li>• Friadent XiVE S: D3.0, D3.4, D3.8, D4.5, D5.5</li> <li>• Nobel Biocare Active Internal: NP (3.5mm), RP (4.3mm, 5.0mm)</li> <li>• Nobel Biocare</li> </ul>	<p>attachment to a minimum of two (2) implants.</p> <p>ISUS Implant Suprastructures are indicated for compatibility with the following implant and abutment systems:</p> <p>Implants:</p> <ul style="list-style-type: none"> <li>• Nobel Biocare Replace Select: NP (3.5mm), RP (4.3mm), WP (5.0mm), and Replace Select 6.0mm</li> <li>• Nobel Biocare Active Internal: NP (3.5mm), RP (4.3mm, 5.0mm)</li> <li>• Zimmer Screw Vent:</li> </ul>		interforaminally.	

Table 6.1	Primary predicate	Reference device	Reference device	Reference device	Reference device
	Subject Device	Predicate Devices			
	DENTSPLY International Inc.  Atlantis™ ISUS	DENTSPLY International Inc.  ISUS Implant Suprastructures  K122424	Nobel Biocare USA, LLC  Procera Implant Bridge Overdenture  K090069	DENTSPLY International Inc.  ANKYLOS SynCone Abutment 5°  K131644	Nobel Biocare USA, LLC  NobelProcera Angulated Screw Channel Abutment Replace K133377
	Replace Select: NP (3.5mm), RP (4.3mm), WP (5.0mm) and Replace Select 6.0 mm <ul style="list-style-type: none"> <li>• Straumann Bone Level: NC (3.3mm), RC (4.1mm, 4.8mm)</li> <li>• Straumann NN (3.5mm), RN (4.8mm), WN (6.0mm)</li> <li>• Zimmer Screw Vent: D3.5, D4.5, D5.7</li> </ul> Abutments: <ul style="list-style-type: none"> <li>• 3i Low Profile Abutment</li> <li>• ANKYLOS Balance Base Abutment D5.5 and Narrow</li> </ul>	1D3.5, D4.5, D5.7 <ul style="list-style-type: none"> <li>• Straumann: NN (3.5mm), RN (4.8mm), WN (6.0mm)</li> <li>• Straumann Bone Level: NC (3.3mm), RC (4.1 mm, 4.8mm)</li> <li>• 3i Internal Connection: D3.4, D4.1, D5, D6</li> <li>• Friadent XiVE S: D3, D3.4, D3.8, D4.5, D5.5</li> </ul> Abutments: <ul style="list-style-type: none"> <li>• Astra Tech- 20° and 45° UniAbutment</li> <li>• Astra Tech UniAbutment EV: 3.6</li> <li>• ANKYLOS Balance Base Abutment D5.5</li> </ul>			

<b>Table 6.1</b>	Primary predicate	Reference device	Reference device	Reference device	Reference device
	<b>Subject Device</b>	<b>Predicate Devices</b>			
	DENTSPLY International Inc.  Atlantis™ ISUS	DENTSPLY International Inc.  ISUS Implant Suprastructures  K122424	Nobel Biocare USA, LLC  Procera Implant Bridge Overdenture  K090069	DENTSPLY International Inc.  ANKYLOS SynCone Abutment 5°  K131644	Nobel Biocare USA, LLC  NobelProcera Angulated Screw Channel Abutment Replace K133377
	Abutment D4.2 <ul style="list-style-type: none"> <li>• ASTRA TECH 20° and 45° UniAbutment</li> <li>• Astra Tech UniAbutment EV 3.6</li> <li>• Friadent XiVE MP D3.8, D4.5, D5.5</li> <li>• Friadent XiVE TG D3.8, D 4.5, D5.5</li> <li>• Nobel Biocare Multi-Unit Abutment RP: 4.0 mm</li> <li>• Straumann Bone Level Angled Abutment: 4.0 mm</li> <li>• Straumann Bone Level: Multi-Base Abutment D3.5, D4.5</li> <li>• Straumann RN (4.8 mm), WN (6.5 mm)</li> <li>• Zimmer Tapered Abutment: 4.5 mm</li> </ul>	and Narrow Abutment D4.2 <ul style="list-style-type: none"> <li>• Nobel Biocare Multi-Unit Abutment RP: 4.0 mm</li> <li>• Zimmer Tapered Abutment: 4.5mm</li> <li>• Straumann RN(4.8mm), WN (6.5 mm)</li> <li>• Straumann Bone Level: Multi-Base Abutment D3.5, D4.5</li> <li>• Straumann Bone Level Angled Abutment:4.0 mm</li> <li>• 3i Low Profile Abutment</li> <li>• Friadent XiVE MP D3.8, D4.5, D5.5</li> <li>• Friadent XiVE TG D3.8, D4.5, D5.5</li> </ul>			

<b>Table 6.1</b>	Primary predicate	Reference device	Reference device	Reference device	
	<b>Subject Device</b>	<b>Predicate Devices</b>			
	DENTSPLY International Inc.  Atlantis™ ISUS	DENTSPLY International Inc.  ISUS Implant Suprastructures  K122424	Nobel Biocare USA, LLC  Procera Implant Bridge Overdenture  K090069	DENTSPLY International Inc.  ANKYLOS SynCone Abutment 5°  K131644	Nobel Biocare USA, LLC  NobelProcera Angulated Screw Channel Abutment Replace K133377
<b>Design</b>					
Prosthesis Attachment	Screw-retained, Friction-fit	Screw-retained	Screw-retained	Friction-Fit	Screw-retained
Restoration	Multi-unit	Multi-unit	Multi-unit	Multi-unit	Single, Multi-unit
Platform Diameter	3.0 - 6.5	3.0 - 6.5	3.3 - 6.5	4.0	3.5-5.0
Abutment Angle	Straight, up to 30°	Straight, up to 30°	Straight	Straight, up to 30°	Straight, up to 59°
Screw Access Angle	Straight, up to 30°	Straight	Straight	Straight	Straight, up to 30°
Connection	Internal	Internal	Internal	Internal	Internal
<b>Material</b>					
Supra-structure	Titanium, Cobalt Chromium	Titanium, Cobalt Chromium	Titanium alloy, Cobalt Chromium	Gold alloy (counterpart)	Titanium alloy
Screw	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy

<b>Table 6.1</b>					
		Primary predicate	Reference device	Reference device	Reference device
	<b>Subject Device</b>	<b>Predicate Devices</b>			
	DENTSPLY International Inc.  Atlantis™ ISUS	DENTSPLY International Inc.  ISUS Implant Suprastructures  K122424	Nobel Biocare USA, LLC  Procera Implant Bridge Overdenture  K090069	DENTSPLY International Inc.  ANKYLOS SynCone Abutment 5°  K131644	Nobel Biocare USA, LLC  NobelProcera Angulated Screw Channel Abutment Replace K133377
Reason for adding the predicate device	Subject Device	Primary Predicate Device	In this reference predicate device the 20 mm cantilever was introduced. In the Subject Device the cantilever is 15 mm.	In this reference predicate device the conical connection was introduced and it is a predicate for the Friction-Fit concept for the 2in1 product described in the Subject Device.	In this reference predicate device the Angulated Screw Access was introduced and it is a predicate for that feature in the Subject Device.

### Biocompatibility

The results of biocompatibility testing conducted for the predicate device, ISUS Implant Suprastructures (K122424) are valid, therefore, no additional biocompatibility testing has been performed.

### Non-Clinical Performance Data

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included static and dynamic compression-bending testing according to ISO 14801 *Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants* (2007) and torque testing. This includes testing of the 2in1 design. Results of the fatigue testing support substantial equivalence in fatigue performance. Screw torque testing shows that sufficient torque can be applied in situations with angulated screw access.

No clinical performance data were submitted.

### Conclusion Regarding Substantial Equivalence

The data included in this submission demonstrate substantial equivalence to the predicate devices, ISUS Implant Suprastructures (K122424), Procera Implant Bridge Overdenture (K090069), ANKYLOS SynCone Abutment 5<sup>0</sup> (K131644) and NobelProcera Angulated Screw Channel Abutment Replace (K133377) listed above. The proposed device has the same intended use, is composed of the same or similar materials, and is characterized by the same fundamental product technology as the predicate devices, K122424, K090069, K131644 and K133377. Any differences in the technological characteristics between the subject and predicate devices do not raise different issues of safety or effectiveness.