

**SECTION 5. 510(k) SUMMARY**  
**for**  
**ISUS Implant Suprastructures**

JUL 5 2013

5.1 Submitter Information:

DENTSPLY International  
Susquehanna Commerce Center  
221 West Philadelphia Street  
York, PA 17405

Contact Person: Helen Lewis  
Telephone Number: 717-849-4229  
Fax Number: 717-849-4343

Date Prepared: June 20, 2013

5.2 Device Name:

- Proprietary Name: ISUS Implant Suprastructures
- Classification Name: Endosseous dental implant abutment.
- CFR Number: 21CFR 872.3630
- Device Class: II
- Product Code: NHA

5.3 Predicate Device:

CAM StructSURE® Overdenture Bar – K101582  
Procera® Implant Bridge Overdenture – K090069  
FRIALIT-2® EstheticBase Abutments - K013438

5.4 Description of Device:

The ISUS Implant Suprastructures are metallic dental restorative devices which are intended for attachment by screw retention to dental implants to aid in the treatment of partially and totally edentulous patients for the purpose of restoring chewing function. The ISUS system consists of the Suprastructure devices themselves as well as retention screw accessories which facilitate their attachment to the dental implants.

The design of the ISUS Implant Suprastructures is derived from models of patient dentition which are produced by the dental professional using standard dental techniques. The dental models are converted to digital representations by DENTSPLY to facilitate DENTSPLY's Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) of the customized, patient-specific ISUS Implant Suprastructure.

The ISUS Implant Suprastructures consist of three (3) device types:

- Bars – Intended to act as a supporting structure to facilitate attachment of removable dental prostheses.
- Bridges – Intended for direct veneering using dental ceramics or resin composites resulting in a fixed, screw-retained prosthesis.
- Hybrids – Intended as a metallic substructure to which finished dentures are bonded to form a fixed prosthesis.

The ISUS Implant Suprastructures are manufactured in versions composed of titanium and cobalt-chromium alloy and feature customized designs derived from individual patient dental impressions.

### 5.5 Indications for Use:

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 attachment to a minimum of two (2) implants.

ISUS Implant Suprastructures are indicated for compatibility with the following implant and abutment systems:

#### Implants:

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

#### Abutments:

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

## 5.6 Description of Safety and Substantial Equivalence:

### Technological Characteristics.

The ISUS Implant Suprastructures are customized metallic restorative devices. The CAD design of the devices is derived by DENTSPLY from individual patient dental impressions produced by dental professionals. The fabrication of the devices is performed by DENTSPLY using automated CAM manufacturing methods. The ISUS Implant Suprastructures feature the following technical characteristics:

- Screw retained with connection to dental implants or abutments.
- Unalloyed, commercially-pure (CP) titanium or cobalt-chromium alloy construction.
- Fabricated from homogenous, single-block raw material (CP titanium or cobalt-chromium alloy).

### Non-Clinical Performance Data.

Dynamic fatigue testing was conducted to evaluate the mechanical integrity of the ISUS device constructs. Representative worst-case test samples were constructed and subjected to cyclic loading in a simulated, implant-supported construct. Dynamic testing was conducted according to the method described in ISO 14801:2007 (*Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*). The results of the dynamic testing were compared to the results of equivalent testing which was conducted on legally marketed predicate dental abutments as well as to published *in vitro* data regarding maximum bite and chewing forces in edentulous patients. The results of the dynamic fatigue testing showed that the lowest fatigue strength of the ISUS Implant Suprastructures supports substantial equivalence.

Additionally, the materials which comprise the the ISUS Implant Suprastructures have been tested according to ISO 22674:2006 (*Dentistry – Metallic materials for fixed and removable restorations and appliances*) and ISO 9693:1999 (*Metal- ceramic dental restorative systems*) to verify that the requirements for: chemical composition, proof strength, elongation after fracture, corrosion resistance, linear thermal expansion, and metal-ceramic bond strength are met. The results of the testing showed that the materials of which the ISUS Implant Suprastructures are composed conform to the requirements for these characteristics as specified in the relevant standards.

Recommended sterilization parameters which have been validated according to ISO 17665-1: 2006 (*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 17665-2: 2009 (*Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1*) are provided in accordance with ANSI/AAMI ST79:2010 (*Comprehensive guide to steam sterilization and sterility assurance in health care facilities*).

Clinical Performance Data.

Not applicable. No human clinical study was performed to support substantial equivalence.

Conclusion as to Substantial Equivalence

The proposed ISUS Implant Suprastructures are substantially equivalent to the predicate Biomet 3i CAM StrucSURE Overdenture Bar (K101582) and Procera® Implant Bridge Overdenture (K090069). The proposed devices have the same intended use and indications for use, are composed of the same or similar materials, and are characterized by the same fundamental product technology as the predicate devices. Testing has been conducted on the materials which compose the ISUS Implant Suprastructures and the results show conformity to the relevant standards for the properties which were studied. Additionally, *in vitro* test data has been included to confirm the mechanical integrity of the ISUS Implant Suprastructures through dynamic fatigue testing in representative worst case constructs. The fatigue strength results for the ISUS Implant Suprastructures support substantial equivalence.



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

July 5, 2013

Ms. Helen Lewis  
Director, Corporate Regulatory Affairs  
DENTSPLY International, Incorporated  
Susquehanna Commerce Center  
221 West Philadelphia Street  
YORK PA 17405

Re: K122424

Trade/Device Name: ISUS Implant Suprastructures  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: II  
Product Code: NHA  
Dated: March 26, 2013  
Received: March 27, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Lester W. Schultheis Jr  
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Acting for  
Kwame Ulmer, M.S.  
Acting Division 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 (if known): K122424

Device Name: ISUS Implant Suprastructures

##### Indications for Use:

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##### Abutments:

- ASTRA TECH 20° and 45° UniAbutment:
- ASTRA TECH UniAbutment EV: 3.6
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- 3I Low Profile Abutment
- Friadent XiVE MP D3.8, D4.5, D5.5
- Friadent XiVE TG D3.8, D4.5, D5.5

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)

Sheena A. Green, S  
2013.07.01 14:42 -04'00'

for M. Susan Runner, DDS,  
MA

**(Division Sign-Off)**  
**Division of Anesthesiology, General Hospital**  
**Infection Control, Dental Devices**

510(k) Number:  K122424