510(k) Summary K111935 FEB 17 2012

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Contact Person:	Dirk Jahn
Date Prepared:	June 29, 2011
Device Trade Name:	Ti-Base Abutment 2-CONnect Abutment
Common Name:	Dental Abutments
Classification Name, Number & Product Code:	Abutment, Implant, Dental, Endosseous 872.3630 NHA
Predicate Devices:	**(K100152)** Sirona Dental Systems Sirona Dental CAD/CAM System, **(K083871)** Atlantis™ Straumann Bone Level Abutment, **(K093483)** Atlantis™ Abutment for Nobel Active Implant, **(K072642)** Biomet 3I Dental Abutments And Restorative Components, **(K990342)** synOcta® Prosthetics, **(K080239)** P.004 Abutments, **(K072570)** NobelActive™Multi Unit Abutment
Device Description and Statement of Intended Use	The Ti-Base Abutment is a premanufactured prosthetic component supplied in two parts, the abutment and screw, for fixation onto dedicated endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. The 2-CONnect Abutment consists of 1 Abutment with screw (for fixation of abutment to the implant) and 1 titanium cap with 1 tiny screw (fixed into the hollow Abutment screw). The cap on top fits exactly to the abutment-geometry and does not have a rotation fixation, so it is easier to work with (not indicated for single crowns but strictly for bridges). The 2-CONnect is intended for use as an aid in prosthetic rehabilitation. The NT-Trading Ti-Base and 2-CONnect is compatible with commercially available dental CAD/CAM systems, such as 3Shape, Exocad, Dental Wings. Such systems must be validated by the user. Indication for use: **Ti-Base Abutments**: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The Ti-Base abutments are intended for use 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 the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Ti-Base abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Nobel Biocare NobelActive™
- Biomet 3i® Osseotite®
- Biomet 3i® Osseotite® Certain®
- Nobel Biocare Branemark®
- Straumann® synOcta®
- Straumann® Bone Level®
- Zimmer® Tapered Screw-vent®
- Astra Tech OsseoSpeed®
- Dentsply-Friadent® Frialit®

2-CONnect Abutments: 2-CONnect abutment is indicated for use to provide support for prosthetic restorations such as bars and bridges. The 2-CONnect abutments can be used in multiple tooth restorations. The 2-CONnect abutment can be used together with cemented bridges and bar constructions for functional and aesthetical reconstruction.
The 2-CONnect abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Straumann® synOcta®
- Straumann® BoneLevel®

Summary of Technological Characteristics

The proposed Ti-Base abutments and 2-CONnect abutments are substantially equivalent to the currently cleared devices. They are substantially equivalent in intended use, material and connection interfaces to the implants are identical for each individual diameter and connection type. Comparison Demonstrating Substantial Equivalence follows at the end of this section.

Testing Summary
In order to demonstrate compatibility of Ti-Base and 2-CONnect abutments to each implant system, fatigue testing was performed according to ISO 14801 Dentistry-Implants-Dynamic fatigue test for endosseous implants. Testing was performed on the abutments in this submission with the implants that they are intended to fit. See section 18.

Conclusion

The information discussed above demonstrates that the NT-Trading Ti-Base Dental Abutments and 2-CONnect Abutments are substantially equivalent to the predicate devices.

Declarations

- This summary includes only information that is also covered in the body of the 510(k).
- This summary does not contain any puffery or unsubstantiated labeling claims.
- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.
- This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	Ti-Base and 2-CONnect	Sirona Dental Systems Sirona Dental CAD/CAM System	Atlantis™ Straumann Bone Level Abutment	Atlantis™ Abutment for Nobel Active Implant	Biomet 3I Dental Abutments And Restorative Components	synOcta® Prosthetics	P.004 Abutments	NobelActive™ Multi Unit Abutment
510(k) Number		K100152	K083871	K093483	K072642	K990342	K080239	K072570
Manufacturer	Nt-Trading GmbH & Co. KG	Sirona Dental Systems GmbH	Astra Tech Inc.	Astra Tech Inc.	Biomet 3I, Inc.	Straumann® USA	Straumann® Manufacturing, Inc	Nobel Biocare® AB
Classification # & Product Code	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA
Intended Use	Ti-Base Abutments: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The Ti-Base abutments are intended for use 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 the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function	The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic reconstruction. 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 the mandible or maxilla. The prosthesis can be cement	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 the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	BIOMET 3i Dental Abutments and Overdenture Bars are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. These are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.	ITI Dental implants are intended to be placed in the maxillary and/or mandibular arch to support crowns, bridges or overdentures in edentulous or partially edentulous patients. The prosthetic accessories to dental implants are used either in the process of fabricating the prosthetic restoration for the implant or as part of the prosthetic restoration.	Abutments are placed into dental implants to provide support for prosthetic restorations such as crowns, bridges and overdentures. Abutments can be used in single tooth replacements and multiple tooth restorations. The subject abutments are for permanent screw-retained bridges and bar-retained implant-borne dentures. Permanent copings are intended to	Nobel Biocare's Multi-Unit is a premanufactured prosthetic component directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation.

	intended to secure the abutment to the endosseous implant. The Ti-Base abutments are indicated for use with the following implant systems: • Nobel Biocare® Replace Select® • Nobel Biocare NobelActive™ • Biomet 3i® Osseotite® • Biomet 3i® Osseotite® Certain® • Nobel Biocare Branemark® • Straumann® synOcta® • Straumann® Bone Level® • Zimmer® Tapered Screw-vent® • Astra Tech OsseoSpeed® • Dentsply-Friadent® Frialit® **2-CONnect Abutments**: 2-CONnect abutment is indicated for use to provide support for prosthetic restorations such as bars and bridges. The 2-CONnect abutments can be	and aesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems: • Nobel Biocare Replace • Nobel Biocare Branemark • Friadent Xive • Biomet 3i Osseotite • Astra Tech Osseospeed • Zimmer Tapered Screw-Vent • Straumann SynOcta	retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.				serve as a base for multi-unit bar or bridge restorations. Temporary Copings are intended to serve as a base for temporary restorations for up to 6 month. Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.	

	used in multiple tooth restorations. The 2-CONnect abutment can be used together with cemented bridges and bar constructions for functional and aesthetical reconstruction. The 2-CONnect abutments are indicated for use with the following implant systems: • Nobel Biocare® Replace Select® • Straumann® synOcta® • Straumann® BoneLevel®							
Abutment Diameter min. Diameter max.	3.5 mm 6.5 mm	Same	Same	Same	Same	Same	Same	Same
Abutment Height	Ti-Base: 4 mm 2-CONnect: 2.3 / 4.3 mm	Same	4 / 5.5 mm	6.6 mm	7.0	1.5 / 6.0	1.5 / 6.0	1.0 / 5.5 mm
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw retained	Screw retained	Screw retained
Reusable	No	No	No	No	No	No	No	No
Material	Ti-6Al-4V	Ti-6Al-4V	Ti-6A1-4V ELI	Ti-6A1- 4V ELI	Ti-6Al-4V	Titanium, Titanium alloy	Ti-6Al-4V	Titanium Alloy

For the reasons stated above, we believe a determination of substantial equivalence between the Ti-Base and 2-CONnect and these predicate devices is appropriate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NT-Trading GmbH & Company AG
C/O Mr. William Greenrose
President
Qserve America, Inc.
220 River Road
Claremont, New Hampshire 03743

FEB 17 2012

Re: K111935
Trade/Device Name: Ti-Base for Individual milled Zirconium Abutment, 2-CONnect Abutment for Bridges and Bars
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 28, 2011
Received: February 14, 2012

Dear Mr. Greenrose:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111935

Device Name: Ti-Base for individual milled Zirconium Abutment, 2-CONnect Abutment for Bridges and Bars

Indications For Use:

Ti-Base for individual Zirconium Abutments: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration.

The Ti-Base for individual Zirconium Abutments are intended for use 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 the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

The Ti-Base abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Nobel Biocare NobelActive™
- Biomet 3i® Osseotite®
- Biomet 3i® Osseotite® Certain®
- Nobel Biocare Branemark®
- Straumann® synOcta®
- Straumann® Bone Level®
- Zimmer® Tapered Screw-vent®
- Astra Tech OsseoSpeed®
- Dentsply-Friadent® Frialit®

2-CONnect Abutment for Bridges and Bars: 2-CONnect Abutment for Bridges and Bars is indicated for use to provide support for prosthetic restorations such as bars and bridges. The 2-CONnect abutments can be used in multiple tooth restorations. The 2-CONnect abutment can be used together with cemented bridges and bar constructions for functional and aesthetical reconstruction.
The 2-CONnect abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Straumann® synOcta®
- Straumann® BoneLevel®

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K111935