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