K103291 NOV - 4 2011

510(k) Summary
21 CFR 807.92

Submitter's Name & Address

Manufacturer: BioHorizons Implant Systems, Inc.
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Official contact: Michael Davis, Regulatory Affairs Manager
Date prepared: November 4, 2011

Name of the Device

Trade Name: BioHorizons Laser-Lok® Abutments for Nobel Biocare™
Common or Usual Name: Dental implant abutment
Classification Name: Endosseous dental implant abutment
Classification Number: Class II (21 CFR 872.3630)

Predicate Devices

1. BioHorizons Simple Solutions with Laser-Lok, documented under 510(k) number K100985, concurrence date of September 9, 2010.
2. Astra Tech Atlantis Abutment in Zirconia for Nobel Replace Implant, documented under 510(k) number K091920, concurrence date of September 28, 2009.
3. Pou Yu Biotechnology TDS Abutment for Nobel Biocare Replace, documented under 510(k) number K091026, concurrence date of June 24, 2009.
4. Inclusive Dental Solutions Titanium Abutment Blanks, documented under 510(k) number K083192, concurrence date of March 4, 2009.
5. Zimmer Dental Ti Prepable Abutment, documented under 510(k) number K092403, concurrence date of October 30, 2009.
6. Altatec GmbH CAMLOG Implant System Abutments, documented under 510(k) number K073553, concurrence date of March 5, 2008.
7. Neoss Ltd. various Titanium Abutments, documented under 510(k) number K071838, concurrence date of October 19, 2007.
8. Altatec GmbH CAMLOG Implant System Modified Implants and Abutments, documented under 510(k) number K083496, concurrence date of January 30, 2009.
9. Sirona Dental CAD/CAM System, documented under 501(k) number K100152, concurrence date of October 22, 2010.
10. Thommen Medical AG SPI Titanium Base for CAD/CAM, documented under 510(k) number K102804, concurrence date of April 20, 2011.
11. Nobel Biocare NOBELSPEEDY™ Implants, documented under 510(k) number K050406, concurrence date of June 8, 2005.
12. Nobel Biocare Groovy Implants, documented under 510(k) number K050258, concurrence date of April 19, 2005.
13. Nobel Biocare Endosseous Implants, documented under 510(k) number K041661, concurrence date of August 26, 2004.

Device Description

BioHorizons Laser-Lok Abutments for Nobel Biocare™ are a series of machined titanium endosseous dental implant healing abutments and final restorative abutments supplied in platform diameters of 3.5mm, 4.3mm and 5.0mm which are compatible with the internal tri-channel connection of Nobel Biocare™ endosseous dental implants. The series includes Simple Solutions Abutments, Custom Titanium Abutments and Titanium Base Abutments.

Abutment material is titanium alloy as specified in ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

The devices are further processed by applying patterns of micro-machined grooves or channels, known as Laser-Lok, to a specified portion of the abutment margin. The product is packaged using materials known in the industry to be appropriate for medical device packaging. Devices labeled 'STERILE' are provided with a minimum sterility assurance level of 10^{-6}, validated in compliance with ANSI/AAMI/ISO 11137-1 *Sterilization of healthcare products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.*

Intended Use

BioHorizons Laser-Lok Abutments for Nobel Biocare™ are intended for use with dental implants as a support for single or multiple unit prostheses in the maxilla or mandible of partially or fully edentulous patients. The abutments are compatible for use with Nobel Biocare™ NobelReplace™ Straight Groovy™, NobelReplace™ Tapered Groovy™, NobelSpeedy™ Replace™, Replace™ Select Tapered and Replace™ Select Straight implants with 3.5mm (NP), 4.3mm (RP) and 5.0mm (WP) platform diameter internal tri-channel connections. The abutment screw is intended to secure the abutment to the endosseous implant.

BioHorizons Laser-Lok Titanium Base Abutments for Nobel are intended to be used as straight abutments.

Compatibility Testing

Compatibility testing was performed on a representative subset of Nobel Biocare™ tri-channel implants. The subset included the following Nobel Biocare™ item numbers: 32161 (NP), 32212 (NP), 32213 (NP), 32215 (RP), 32216 (RP), 32217 (RP) and 32221 (WP). This testing verifies compatibility with all Nobel Biocare™ items listed in the following table based on equivalent mating platform geometry.

Platform	Nobel Biocare™ Implants	Laser-Lok Custom Ti Abutments	Laser-Lok Titanium Base Abutments	Simple Solutions Healing Abutments	Simple Solutions Abutments	
3.5mm Internal Tri-Channel Connection	NP Platform Implants	NB-BPANPL	NB-NPTBL	NB-33449 NB-33450 NB-NPHA28	NB-35962 NB-35966 NB-NP4028	NB-35798 NB-35802 NB-NP5528
4.3mm Internal Tri-Channel Connection	RP Platform Implants	NB-BPARPL	NB-RPTBL	NB-33451 NB-33452 NB-RPHA28	NB-35963 NB-35967 NB-RP4028	NB-35799 NB-35803 NB-RP5528
5.0mm Internal Tri-Channel Connection	WP Platform Implants	NB-BPAWPL	NB-WPTBL	NB-33446 NB-33447 NB-WPHA28	NB-35964 NB-35968 NB-WP4028	NB-35800 NB-35804 NB-WP5528

Technological Characteristics

The fundamental scientific technology of the BioHorizons Laser-Lok Abutments for Nobel Biocare™ is substantially equivalent to the referenced predicate devices. The devices are further processed by applying Laser-Lok to a specified region of the abutment margin.

Laser-Lok is a surface feature in which patterns of micro-machined grooves are applied to the abutment margin, providing a roughened surface to establish a physical, connective tissue attachment (unlike Sharpey fiber attachment). This tissue connection:

1) is functionally oriented,
2) inhibits epithelial cell downgrowth and
3) enables crestal bone attachment adjacent to the implant.

All materials, suppliers, processing, packaging and sterilization methods (where applicable) remain the same as those utilized for the predicate BioHorizons Simple Solutions Laser-Lok Abutments (K100985). The BioHorizons Laser-Lok Abutments for Noble Biocare™, which is the subject of this 510(k), are substantially equivalent to all features of the predicate implant devices which could affect safety or effectiveness because of the similarities in design, materials and intended use.

Summary of Testing

The data presented in this 510(k) submission supports the substantial equivalence of the BioHorizons Laser-Lok Abutments for Nobel Biocare™ to the specified predicate devices with respect to performance, safety and effectiveness. A prospective study was conducted in a canine model to evaluate bone and soft tissue healing patterns when Laser-Lok microgrooves are applied to dental implant abutments. The study consisted of four cohorts – Group A: Laser-Lok healing abutment on an RBT implant; Group B: Laser-Lok healing abutment on an RBT implant with a machined area; Group C: Machined healing abutment on an RBT implant; and Group D: Machined healing abutment on an RBT implant with a machined area. Laser-Lok and machined-surface healing abutments were randomly assigned to internal-connection implants that were either fully RBT-treated or RBT-treated with a 0.3mm machined collar. Each group received nine implants with abutments placed at the time of surgery. The results demonstrate significant improvement in peri-implant hard and soft tissue healing on the Laser-Lok healing abutments as compared to traditional machined abutment surfaces.

Nevins *et al* concluded that the presence of the 0.7-mm laser-ablated microchanneled zone consistently enabled intense fibroblastic activity to occur on the abutment-grooved surface, resulting in an interlacing complex of connective tissue fibers oriented perpendicular to the abutment surface that served as a physiologic barrier to apical JE migration.

Conclusion

The clinical and nonclinical data presented in this submission indicates that the new devices are safe and effective for their intended use and perform as well or better than the referenced predicate devices.

· 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

NOV - 4 2011

Mr. Michael Davis
Regulatory Affairs Manager
BioHorizons Implant Systems, Incorporated
2300 Riverchase Center
Birmingham, Alabama 35244

Re: K103291
Trade/Device Name: BioHorizonz Laser-Lok® Abutments for Nobel Biocare™
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 26, 2011
Received: October 27, 2011

Dear Mr. Davis:

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: K103291

Device Name: BioHorizons Laser-Lok® Abutments for Nobel Biocare™

Indications for Use:

BioHorizons Laser-Lok Abutments for Nobel Biocare™ are intended for use with dental implants as a support for single or multiple unit prostheses in the maxilla or mandible of partially or fully edentulous patients. The abutments are compatible for use with Nobel Biocare™ NobelReplace™ Straight Groovy™, NobelReplace™ Tapered Groovy™, NobelSpeedy™ Replace™, Replace™ Select Tapered and Replace™ Select Straight implants with 3.5mm (NP), 4.3mm (RP) and 5.0mm (WP) platform diameter internal tri-channel connections. The abutment screw is intended to secure the abutment to the endosseous implant.

BioHorizons Laser-Lok Titanium Base Abutments for Nobel are intended to be used as straight abutments.

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)

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

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