K102822

Custom Dental Implants

Norwalk, WI 54648

JAN 10 2011

Implant-One
Dental Implants

510(k) Summary

Date:	20 December 2010
Sponsor:	Custom Dental Implants Inc. 18975 Incline Road Norwalk, WI 54648 Phone 608.269.3940
Contact Person:	Thomas Arendt, Vice President
Proposed Trade Name:	Implant-One™ Dental Implants
Device Classification	Class II
Classification Name:	Endosseous dental implant & Endosseous dental implant abutment
Regulation:	872.3640 & 872.3630
Device Product Codes:	DZE & NHA
Device Description:	The Implant-One™ Dental Implants include endosseous dental implants, cover screws, healing caps, dental implant abutments and abutment screws in a variety of sizes to accommodate differing patient anatomy. Endosseous implants are self-tapping, root-form and threaded. They range from 3.25mm to 5.5mm in diameter with lengths ranging from 8mm to 14mm and have an internal, threaded abutment connection having a Morse style taper. Cover screws and healing caps provide protection to the threads of the abutment connection during endosseous and gingival healing. Cover screws are pre-packaged with each implant. Healing caps are provided as an alternative to the cover screw and are packaged separately. Abutment options include Standard and Restorative in various heights. These are fastened to the implant using an abutment screw.
Intended Use:	The Implant-One™ system is indicated for surgical placement in partially or completely edentulous upper or lower jaws to provide a means for prosthetic attachment to restore a patient's chewing function. The Implant-One™ system is indicated for immediate loading only when primary stability is achieved and with the appropriate occlusal loading.
Materials:	The Implant-One™ components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F1472 or stainless steel according to ASTM A582.
Predicate Devices:	Biomet 3i dental implants and abutments (K063341/K072642) Zimmer Screw Vent and Contour Abutment (K061410/K061847) FRIADENT Implant Systems (K073075)

Technological Characteristics: The fundamental scientific technology of the Implant-One™ system is the same as previously cleared devices as shown below.

System:	**Implant-One**	**Biomet 3i**	**Zimmer**	**Ankylos**
Material of manufacture:	Titanium and/or titanium alloy			
Design:				
Endosseous implant	Root-form, Tapered	Root-form, Straight and tapered	Root-form, Straight and tapered	Root-form, Straight
Method of stabilization	Threaded fixation	Threaded fixation	Threaded fixation	Threaded fixation
Range of Diameters	3.25 – 5.5mm	3.25 – 6mm	3.3 – 6mm	3.5 – 7.0mm
Range of Lengths	8 – 14mm	8.5 – 15mm	8 – 16mm	8 – 17mm
Modified surface	Yes, AlO2 blasted	Yes, acid etched	Yes, microtextured or HA coated	Yes, grit blasted and etched
Connection to abutment	Hex alignment, 6° included taper, screw attachment	Hex alignment, screw attachment	Hex alignment, 1° taper, screw attachment	Keyed alignment, friction-lock taper, thread attachment
Abutments	Standard, Ball, Gold coping	Standard, Ball	Standard, Ball, Gold coping	Standard, Ball, Gold coping

Performance Data: Non-clinical dynamic testing of the worst case Implant-One™ system construct was performed according to ISO 14801. The mechanical test results demonstrated that the Implant-One™ system performs as well as or better than the predicate devices. No clinical data was used in support of this submission.

Conclusion: The Implant-One™ system is substantially equivalent to the predicate devices referenced above is therefore safe and effective for its intended use.

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

Custom Dental Implants, Incorporated
C/O Ms. Karen E. Warden
President
BackRoads Consulting, Incorporated
8202 Sherman Road
Chesterland, Ohio 44026

JAN 10 2011

Re: K102822
Trade/Device Name: Implant-One™ System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant & Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: DZE & NHA
Dated: December 21, 2010
Received: December 23, 2010

Dear Ms. Warden:

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

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Indications for Use Statement

510(k) Number: K102822

Device Name: **Implant-One™ System**

Indications for Use:

The Implant-One™ system is indicated for surgical placement in partially or completely edentulous upper or lower jaws to provide a means for prosthetic attachment to restore a patient's chewing function. The Implant-One™ system is indicated for immediate loading only when primary stability is achieved and with the appropriate occlusal loading.

Prescription Use __X__ AND/OR Over-the-Counter Use_____

(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: K102822