K092261

JUL 2 3 2010

Impladent	TECHNICAL EVALUATION DOCUMENTATION	Defcon TSA TSH Dental Implant Systems

SECTION 5 : 510(k) SUMMARY

DATE OF PREPARATION: 2010-07-15

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DEVICE TRADE NAME: IMPLADENT DEFCON TSA / TSH Dental Implant Systems
COMMON NAME: Root-form Endosseous Dental Implant
CLASSIFICATION NAME: Root-form Endosseous Dental Implant (21 CFR 872.3640)

PREDICATE DEVICE(S):
- Straumann Dental Implant System – Straumann Institut (K083550)
- ITI Dental Implant System – Straumann Institut (K033984)
- NobelActive 8.5 mm & 18.0 mm – Nobel Biocare (K083205)
- NobelActive Internal Connection Implant – Nobel Biocare (K071370)
- Various Branemark System Dental Implant Products – Nobel Biocare (K022562)

DEVICE DESCRIPTION:
DEFCON TSA / TSH dental implant systems are threaded, root-form endosseous implants of various diameters and lengths and corresponding abutments. Implants are composed of Titanium commercially pure, feature different implant to abutment connection options and are available with modified surfaces to promote improved osseointegration. Implant abutments are composed of Titanium commercially pure, Titanium alloy 6Al 4V and POM-C.

Primary stability, adequate osseointegration and mechanical performance of the implant connection are fundamental to implant success. Device design characteristics including the thread profile, geometry, surface finish and crestal characteristics are based on these concepts.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:	PROPOSED DEVICES	PREDICATE DEVICES	
		for TSA	for TSH
	DEFCON TSA / TSH Implant System	**K071370** NobelActive Internal Connection Implant **K083205** NobelActive 8.5mm & 18.0mm **K083550** Straumann Dental Implant System **K033984** ITI Dental Implant System	**K022562** Various Branemark System Dental Implant Products
Implant			
Material	Commercially Pure Titanium Grade 2	Commercially Pure Titanium Grade 4	Commercially Pure Titanium Grade 1
Form / Features	Root-form cylindrical-conical, Threaded, Hexagonal & conical Internal connection (TSA) Hexagonal External connection (TSH)	Root-form cylindrical-conical, Threaded, Hexagonal or Octagonal & conical Internal connection	Root-form cylindrical-conical, Threaded, Hexagonal External connection
Range of diameters	Ø prosthetic connection: 3.3 ~6.0 Ø endosseous: 3.3 ~ 5.5	Ø prosthetic connection: 3.5 ~6.5 Ø endosseous: 3.3 ~ 5.0	Ø prosthetic connection: 3.5 ~ 5.1 Ø endosseous: 3.3 ~ 5.0
Range of lengths	8.5 ~16.0	6.0 ~18.0	7.0 ~ 18.0
Surface Treatment	Grit-blasted, acid etched –to increase TiO_2 superficial layer	Electrochemical oxidation process or sand-blasting and acid etching to increase TiO_2 superficial layer.	Electrochemical oxidation process to increase TiO_2 superficial layer
Healing Caps, Screw and Cement Retained Abutments			
Material	Titanium Grade 5 (TiAl6V4 ELI)	Titanium	Titanium
Form / Features	Cylindrical, taper and hexagonal connection (TSA internal; TSH external). Tapered external shape.	Cylindrical, taper and hexagonal or octagonal internal connection. Tapered external shape.	Cylindrical, taper and external hexagonal connection. Tapered external shape.
Range of diameters	Ø prosthetic connection: 3.3 ~ 6.0 Abutment diameter: 4.2 ~ 6.9	Ø prosthetic connection: 3.5 ~ 6.5 Abutment Diameter: 3.6 ~ 5.0	Ø prosthetic connection: 3.0 ~ 5.1 Abutment Diameter: 4.0 ~ 6.0
Range of lengths	0.5 ~ 7.0	1.5 ~ 7.0	1.5 ~ 7.0
Temporary Caps (only available in DEFCON TSA system)			
Material	POM coping, Titanium Grade 5 (TiAl6V4 ELI)	POM coping, Titanium abutment or Polyether ether ketone + Ti.	Not applicable
Form / Features	Conical and post shape. Screw retained. Internal connection. Anatomic emergence for gingival conformation.	Conical and post shape. Internal connection. Screw retained. Anatomic emergence for gingival conformation.	
Range of diameters	Ø prosthetic connection: 3.7 ~ 6.0	Ø prosthetic connection: 3.5 ~6.5	
Range of lengths	1.5 transmucosal height	1.5 ~ 3.0 transmucosal height	
Retentive Anchors for Over dentures			
Material	Titanium Grade 5(TiAl6V4 ELI), EPDM	Titanium, gold	Titanium, rubber
Form / Features	Ball abutment plus o-ring titanium cap.	Abutment plus adjustable retention anchor.	Ball abutment plus o-ring plastic cap.
Range of diameters	Ø prosthetic connection: 3.7 ~ 4.7	Ø prosthetic connection: 3.5 ~ 6.5	Ø prosthetic connection: 3.5 ~ 4.1
Range of lengths	1.0 ~ 5.0 transmucosal height	1.0 ~ 6.0 transmucosal height	1.0 ~ 10.0

(dimensions in mm)

SECTION 5 : 510(k) SUMMARY

INDICATIONS FOR USE:

DEFCON TSA/TSH implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients.
DEFCON TSA/TSH implants are for single-stage or two-stage surgical procedures and cement or screw retained restorations.
Implants are intended for immediate loading on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function if the requirement detailed in the surgical manual is satisfied. When placing implants in the posterior region, we recommend using only large diameter (Ø6.0 mm and above) implants.
Specific indications for small diameter (Ø3.3 mm) implants:
Because of their reduced mechanical stability, small diameter implants are only used in cases with a low mechanical load. Placement in the molar region is not recommended.

NON-CLINICAL TEST SUMMARY

The proposed device has been subject to bench testing to determine conformance to performance specifications and requirements taking account of its intended use as a dental implant system and following all indications set out in FDA Document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".

Functional laboratory testing performed in foreseeable operating conditions showed correct operation of the device as per its intended use, specifically including mechanical performance when subject to fatigue testing, biocompatibility and biological testing in accordance with the level and duration of contact with the human body, surface finish evaluation including chemical analyses, and sterilization process validation.

CLINICAL TEST SUMMARY

No clinical studies are submitted.

CONCLUSIONS:

We believe the intended use, the indications for use and performance of both the proposed IMPLADENT DEFCON TSA/TSH dental implant systems and the predicate dental implant systems are essentially the same.

We conclude that the proposed DEFCON TSA/TSH dental implant systems are safe and effective for its intended use, and based on the information included in this submission, we believe that substantial equivalence of the proposed device with the legally marketed predicate devices may be established.

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

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JUL 23 2010

Re: K092261
Trade/Device Name: IMPLADENT DEFCON TSA/TSH Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 15, 2010
Received: July 21, 2010

Dear Mr. Gutierrez:

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,

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): **K092261**

Device Name: IMPLADENT DEFCON TSA/TSH DENTAL IMPLANT SYSTEM

Indications for Use:

DEFCON TSA/TSH implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients.
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Prescription Use ✓ (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)

Pei Hsu for MSP

ivision Sign-Off)
vision of Anesthesiology, General Hospital
ection Control, Dental Devices

(k) Number: K092261