K111364 FEB - 1 2012

510(K) Summary

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Device Information
Trade Name: HAPTITE Coating Implant System
Common Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form
Product Code: DZE
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: 2011-5-11

General Description

This product is the operating, dental material as placed dental implant to inner part of maxillary to sustain, maintain prosthetic repair tooth or denture, mainbody (structure of subpart) is made by Titanium (Grade 4), is treated as blasting powder, and RBM at room temperature of CaP type to reduce Bone loss to bottom 1mm of the Machine Collar. Also, screw part of below 1 mm is treated as SHS (Super High Speed) RBM HA (Hydroxyapatite) Coating at room temperature. It is connected to structure of upper part as the type of the internal.

HA Thin film coating achieved through the process in which the HA particles impact on the surface of implant with high speed.

By passing carrier gas, which comes from nitrogen tank, through the hopper containing HA particles, the HA particle and carrier gas can flow to the vacuum chamber. The vacuum chamber maintaining low pressure thanks to the vacuum pump, enable to spray the HA particles with carrier gas out in high speed(more than 500m/sec) through spray nozzle. As HA particles impact on the surface of implant, it reduced to fragment and those fragment make up thin film coating layer.

The implant diameters are 3.7, 4.1, 4.3, 4.8, 5.5, 6.0, 6.5, and 7.0 mm and the implant lengths are 7, 8, 9, 10, 12, 14, and 16mm in this system.

The system consists of 2 fixture systems, i-clean fixture and s-clean fixture, and 2 abutment systems i-clean and s-clean abutment.

The i-clean abutment system is composed of healing cap, various abutments (solid, excellent solid, octa, synocta, inocta, temporary, healing, o-ring and free), screws (cover screw,

closing screw, abutment screw, cylinder screw), gold UCLA, gold cylinder,.

The s-clean abutment system is composed of healing cap, various abutments (sole, couple, hex, temporary, o-ring, free, octa, zero margin, freemill, and MOA), and gold cylinder, and various screws (abutment, cylinder).

i-Clean Fixture is Non-submerged type, once surgery and safe structure as having 8° from center of connection part.

s-Clean Fixture is Submerged type, twice surgery and safe structure as having 11° from center of connection part.

The abutment lengths are 7, 8, 9, 10, 11, 12mm, and cuff lengths 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5.5, 7mm.

The i-Clean fixture is available with either tapered, straight, or SAVE body designs. The i-Clean tapered fixture is available in diameters of 3.7, 4.1, 4.3, and 4.7mm and each diameter is available in lengths of 8, 10, 12, or 14mm. The i-Clean straight fixture is available in diameters of 4.05, 4.25, and 4.75mm and each diameter is available in lengths of 8, 10, 12, 14, and 16mm. The i-Clean SAVE fixture is available in diameters of 5.5, 6.0, 6.5, and 7.0mm and each diameter is available in lengths of 7, 8, 9, 10, and 12mm. The i-Clean Tapered II design contains a thread design with differs from the i-Clean Tapered fixture design. The i-Clean Tapered II has no 'micro thread' design.

The s-Clean fixture is available with either tapered, straight, or SAVE body designs. The s-Clean tapered fixture is available in diameters of 3.7, 4.1, 4.3, and 4.8mm and each diameter is available in lengths of 8, 10, 12, or 14mm. The s-Clean straight fixture is available in diameters of 4.1, 4.3, and 4.75mm and each diameter is available in lengths of 8, 10, 12, 14, and 16mm. The s-Clean SAVE fixture is available in diameters of 5.5, 6.0, 6.5, and 7.0mm and each diameter is available in lengths of 7, 8, 9, 10, and 12mm. The s-Clean Tapered II design contains a thread design with differs from the s-Clean Tapered fixture design. The s-Clean Tapered II has no 'micro thread' design.

Indication for Use

The Dentis Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading.

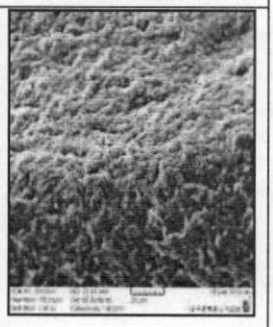
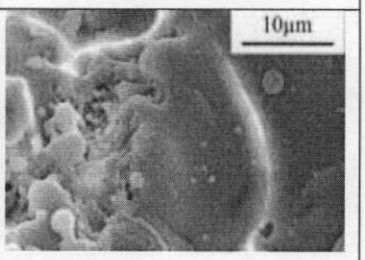
Predicate Devices & Comparison

The subject device is substantially equivalent to the following predicate device:

- DIO BIOTITE-H IMPLANT SYSTEM manufacture by DIO Deparment, DSI (K073070)
- Replace HA coated implant manufactured by Nobel Biocare USA, INC. (K022424)

Testing and other comparisons have established that the subject of HAPTITE implant system is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to the predicate device currently marketed in the U.S.

	Subject device	Predicate device		
Device name	Dentis HAPTITE Implant system	Dentis Implant System	DIO BIOTITE-H IMPLANT SYSTEM	Replace HA Coated Implant
510(k) number	N/A	K082843/ K073486	K073070	K022424
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.	DIO Department, DSI, Inc.	Nobel Biocare USA, Inc.
Intended use	Identical to predicate devices	Identical to predicate devices	The implants are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restoration and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures..	The implants are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restoration and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.
Material	CP. GR.4 ASTM F67	CP. GR.4 ASTM F67	CP. GR.3 and GR.4 ASTM F67	CP. GR.3 and GR.4 ASTM F67
Design	Tapered and straight	Tapered and straight	Tapered	Straight
Implant diameter	3.7, 4.1, 4.3, 4.8, 5.5, 6.0, 6.5 and 7.0mm	3.5, 3.7, 4.1, 4.3, 4.8, 5.1, 5.5, 6.0, 6.5 and 7.0mm	3.8, 4.1, 4.5, 4.8, and 5.3mm	3.5, 4.3, 5.0, 6.0mm
Implant length	7, 8, 9, 10 ,12, 14 and 16mm	7, 8, 10, 12 and 14mm	8-14mm	10,13,16mm
Attachments	Various abutments and components	Various abutments and components	Various abutments and components	Various abutments and components
Surface treatment	HA coating	RBM	HA coating	HA coating
Coating method	Super High Speed Blast Coating Process	Non Coating	Electrochemical[1]	Plasma-sprayed HA coating[2]

Coating thickness	1~2㎛		15±5㎛[1]	>5㎛[2]
Solubility	insoluble		Soluble[1]	Insoluble[2]
Surface chemistry	100% crystalline HA		95% Brushite + 5% hydroxyapatite[1]	Amorphous + crystalline HA[2]
Shear strength	≒37MPa		13MPa[1]	≒37.4MPa
Morphology				
Gamma sterilized	Yes	Yes	Yes	Yes
Product Code	DZE	DZE	DZE	DZE

Non-clinical Testing data

- Measurement of the gap between fixture and abutment, rotational angle tests were successfully performed.
- Shear bonding strength test was successfully performed in accordance with ASTM F 1147, 1044 as the result about 37 MPa over standard 34.5 MPa.
- Tensile bonding strength test was successfully performed in accordance with ASTM F 1147, 1044 as the result about 41 MPa over standard 34.5 MPa.
- HA Coating Implant Graft Test in the pig bone for the evaluation of the stability of the coating layer was successfully performed.
- Roughness, Degree of crystallinity, Porosity, Cross section analysis, Density, Surface area analysis, CaP ratio tests were successfully performed.

Conclusion

The HAPTITE Coating Implant System, subject of this submission, constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. The risks of using the device as recommended pose no greater risks than other implant systems. This system has the same intended use and fundamental scientific technology as its predicate devices. HAPTITE Implant system, as designed and manufactured, is as safe and effective as the predicate devices and therefore is believed to be substantially equivalent to Predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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FEB - 1 2012

Re: K111364
Trade/Device Name: HAPTITE Coating Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: January 30, 2012
Received: January 30, 2012

Dear Ms. Lee:

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.

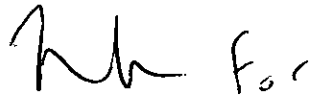
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K111364

Device Name: HAPTITE Coating Implant System

The HAPTITE Coating Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading

Prescription Use ___X_____ AND/OR Over-The-Counter _____
(Part 21 CFR 801 Subpart D) (Per 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)
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111364