K100511

510(K) Summary

JUL - 9 2010

Submitter
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Device Information

Trade Name: Cotec Dental 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: April 30, 2010

General Description

Cotec Dental Implant System is composed of two types of fixtures, internal and submerged and abutments. The sizes of the fixtures in both internal and submerged type are identical, and made of titanium metal intended to be surgically placed in the bone of the upper or lower jar arches. The system is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. This system is made from pure titanium, and the surface treatment of fixtures is done with R.B.M. whereas abutments are not surface treated.

The submerged type implant has an internal morse tapered connection with abutment for stronger engaging and dispersed stress distribution. This means that marginal bone can be perfectly preserved for safety in long term use. There are two types of submerged implant, straight and tapered type. Fixture diameter is Ø3.8, Ø4.2, Ø4.7, Ø5.2mm and the length is 8.0, 10.0, 12.0, 14.0mm. Fixture and cover screw

are made of CP, Ti, Gr4 (ASTM-F67). The abutment is made of Ti6Al4V,ELI(ASTM-F136) , and its diameters are 3.8 – 5.2 mm and the length is 5.5 – 7.5mm.

Indication for Use

The Cotec Dental 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 not intended for immediate loading.

Predicate Devices & Comparison

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

- SQ IS System (Neobiotech Co., Ltd.; K090825)
- SQ IT System (Neobiotech Co., Ltd.; K090527)

Testing and other comparisons have established that the subject of Cotec Dental Implant System is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to other predicate devices of the type currently marketed in the U.S.

	Subject Device	Predicate Device	
510(K) Number	N / A	K090825	K090527
Device Name	Cotec Dental Implant System	SQ IS System	SQ IT System
Manufacturer	Cotec Implant Co., Ltd.	Neobiotech Co., Ltd.	Neobiotech Co., Ltd.
Indications for Use	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories
Design	Flat shoulder Internal and flat shoulder submerged Implant Design with a narrower shape towards the bottom	Similar to flat shoulder submerged implant design with a narrower shape towards the bottom	Similar to flat shoulder internal implant design with a narrower shape towards the bottom
Endosseous Implant Material	CP. Ti. Gr. 4 ASTM-F67	CP. Ti. Gr. 4 ASTM-F67	CP. Ti. Gr. 4 ASTM-F67
Implant Sterile	Yes	Yes	Yes
Implant Sterilization Method	Gamma	Gamma	Gamma
Abutment and cover screw sterilization method	Non-sterile	Non-sterile	Non-sterile

Surface Treatment		RBM (Resorbable Blasting Media)	RBM (Resorbable Blasting Media)	RBM (Resorbable Blasting Media)
Implant	Diameters	3.8 - 5.2 mm	3.5 – 8.0 mm	3.5 – 6.0 mm
	Lengths	8 – 14 mm	7 – 15 mm	8 – 15 mm
Abutment	Diameters	3.8 - 5.2mm	3.5 - 8.0mm	3.5 - 6.0mm
	Lengths	5.5 - 7.5mm	4.0 - 8.0mm	4.0 - 8.5mm
Cover screw	Diameters	3.32mm	3.19 – 3.43mm	3.5 - 3.6mm
	Cuff lengths	3.0mm	3.0mm	3.0mm
Attachments		Various abutments and components	Various abutments and components	Various abutments and components
Abutment Material		Ti6Al4V, ELI, ASTM-F136	Ti6Al4V, ELI, ASTM-F136	Ti6Al4V, ELI, ASTM-F136
Cover Screw Material		CP. Ti. Gr. 4 ASTM-F67	CP. Ti. Gr. 4 ASTM-F67	CP. Ti. Gr. 4 ASTM-F67
Product Code		DZE	DZE	DZE

Performance Data and

We have conducted the following tests. All of the data consistent with the recommendations in the FDA guidance document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, May 12, 2004. The following tests have demonstrated that there is substantial equivalence in the performance, safety and effectiveness between the Cotec Implant System and the referenced predicate devices and it has proved that the Cotec implant system meets its predefined acceptance criteria and performs in accordance with its intended use. Test samples refer to the devices included in this system.

- Acute systematic toxicity test: This test proved the test samples are safe without having any systematic toxicity.
- Appearance test: this test conducted by macroscopic examination of external appearance of test samples. No fracture, deformation crack has been found. This test proved the test samples are safe.
- cytotoxicity test: As a result for this test, the test samples are indicated to be safe to be used.
- intracutaneous reactivity test : Based on the collected data, this test samples are proved to be safely acceptable rate for intracutaneous reactivity.
- pyrogen test: As a result, this test proved that the test samples are safe with higher than body temperature.
- Sensitization test: In this study, the test samples are proved to be safe with having no indications of erythema or oedema on guinea pig skin.
- Sterility test: To examine the activity of bacteria, this test has been conducted. As a result, there were no indications of bacterial activity, thus the test samples are proved to be safe to be used.

Safety and Effectiveness

This device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device. It has been shown in this 510(k) submission that the differences between the Cotec Dental Implant System and the predicate devices do not raise any questions regarding its safety and effectiveness. The Cotec Dental Implant system, as designed and manufactured, is as safe and effective as the predicate devices and therefore is determined to be substantially equivalent to the referenced predicate devices.

Conclusion

The Cotec Dental Implant System, subject of this submission, constitutes a safe, reliable and effective medical device, meeting all the declared requirements of its intended use. Device presents no adverse health effects or safety risks to patients when used as intended. The Cotec Dental Implant System has the same intended use and fundamental scientific technology as its predicate devices - the SQ IS System (K090825) and SQ IT System (K090527) by Neobiotech Co., Ltd. Therefore, Cotec Dental Implant System and its predicate devices are believed to be substantially equivalent.

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

Cotec Implant Company Limited
C/O Ms. Joyce Bang
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13340 East Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

JUL - 9 2010

Re: K100511
Trade/Device Name: Cotec Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 24, 2010
Received: June 25, 2010

Dear Ms. Bang:

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): K100511

Device Name: Cotec Dental Implant System

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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)

Ken Mulay for NSR

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

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