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510(K) Summary K08_____.

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WARANTEC Co., Ltd.
307, Sunil Technopia, #440, Sangdaewon-dong,
Jungwon-gu, Sungnam-si,
Gyeonggi-do, 462-726, Korea
TEL. +82-31-777-3026~8
FAX. +82-31-777-3025
Contact: Song, Chung-Hun/ President
Date prepared: June 10, 2008

1. Trade Name: ONEPLANT Dental Implant System

2. Common Name: Dental Implant

3. Classification Name and Device Class: implant, endosseous, root-form DZE and Abutment, implant, dental, endosseous NHA; Class II per regulations 872.3640 and 872.3630

4. The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : DENTIUM Multiple: K070228; K052957; K060501; K052823; K041368, Osstem Implant K051576

5. Description of device: Dental implant systems are devices made of a material such as titanium intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices such as artificial teeth, and to restore the patients chewing function. Dental implant system consists of Fixture, Abutment and Implant surgical instruments.

6. Indications for use: ONEPLANT is designed for use in dental implant Surgery. These are intended for use in partially or fully edentulous mandibles and maxillae to support for single or multiple-unit restorations such as cemented retained, screw retained, or over denture restorations and terminal or intermediate abutment support for fixed bridgework.

7. Comparison Table: Below.

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Manufacturer/510(k) Number		DENTIUM Multiple: K070228; K052957; K060501; K052823; K041368	Osstem Implant K051576	WARANTEC
Website		www.implantium.com	www.osstem.com	www.oneplant.co.kr
Type name		**IMPLANTIUM**	**GS System**	**ONEPLANT**
Intended use		It is to provide support for prosthetic device, such as artificial teeth, and to restore the patient's chewing function	GS 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. GS System is for one stage surgical procedures. It is not intended for immediate load.	ONEPLANT is designed for use in dental implant Surgery. These are intended for use in partially or fully edentulous mandibles and maxillae to support for single or multiple-unit restorations such as cemented retained, screw retained, or over denture restorations and terminal or intermediate abutment support for fixed bridgework.
Design		Internal Connection Morse Taper, Internal Octagon	Internal Connection Morse Taper, Internal Octagon	Internal Connection Morse Taper, Internal Octagon
Fixture	Material	Titanium G4	Titanium G4	Titanium G4
	Platform Dia.	3.6, 4.0, 4.5, 5.0, 5.5mm	3.5, 4.0, 4.5, 5.0mm	3.3, 3.6, 4.3, 5.3mm
	Length	8, 10, 12, 14mm	7, 8.5, 10, 11.5, 13, 15mm	8.5, 10, 11.5, 13, 15mm
Abutment	Material	Titanium G5	Titanium G5	Titanium G5
	Type	Various	Various	Various
Certification		KGMP, CE, FDA 510k	KGMP, CE, FDA 510k	KGMP

8. **Conclusion: In all respects, the Oneplant Dental Implant components are the equivalent of currently marked devices. They are made of the same materials and have similar dimensions and characteristics. This device is substantially equivalent in design, material, intended use and function to the products on the table above.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2009

Warantec Company, Limited
C/o Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K081748
Trade/Device Name: Oneplant Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 16, 2009
Received: March 19, 2009

Dear Mr. Kamm:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting 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

510(k) Number (if known):_____

Device Name: Oneplant Dental Implant System

Indications For Use:
ONEPLANT is designed for use in dental implant Surgery. These are intended for use in partially or fully edentulous mandibles and maxillae to support for single or multiple-unit restorations such as cemented retained, screw retained, or over denture restorations and terminal or intermediate abutment support for fixed bridgework..

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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: K081748