510(k) Summary
(K122804)

MAY 2 0 2013

The summary of 510(k) safety and effectiveness information is being submitted in accordance with requirement of 21 CFR Part 807.92

Date :	May 20, 2013
Submitter : :	INTAI TECHNOLOGY CORP.
Address :	No.9, Jingke Rd., Nantun Dist . Taichung City, Taiwan Tel : 886-4-3601-5336 Fax: 886-4-3601-9772
Contact Person :	Kevin Wang, Regulatory Affairs Specialist
Trade Name :	Royal-Dent Eureka Dental Implant System
Device Classification :	Class II
Classification Name :	Endosseous dental implant, Endosseous dental implant abutment
Regulation Number :	872.3640, 872.3630
Product Code :	DZE, NHA
Predicate Devices :	GS System (K063861) GS III System (K091208)
Device Description :	Royal-Dent Eureka Dental Implant System is a multiple component device, made from CP Ti and Ti-6Al-4V, which allow the surgeon to build an implant system to fit the patient's requirements. The system is a set of implants designed to be inserted into the upper and/or lower jawbone and serves as a replacement for patient's tooth providing a stable foundation for restorations. The system is provided with simplified main implants, but with a variety of different styles of components. Eureka and Eureka Plus implant series are the sub-types incorporated into Royal-Dent Dental Implant System. The major difference between two implant sub-types is outer design configuration. The design configuration and features of inner hole for the sake of fitness to various screws and abutments are identical. The Implants are provided sterile, the remaining components must be sterilized prior to use. The size information is as below. **Eureka Implant** Dia. 3.5mm x (L) 8.5mm, 10mm, 11.5mm, 13mm, 15mm. Dia. 4.0mm x (L) 8.5mm, 10mm, 11.5mm, 13mm, 15mm. Dia. 4.5mm x (L) 8.5mm, 10mm, 11.5mm, 13mm, 15mm. Dia. 5.0mm x (L) 8.5mm, 10mm, 11.5mm, 13mm, 15mm. **Eureka Plus Implant** Dia. 3.5mm x (L) 8.5mm, 10mm, 11.5mm, 13mm, 15mm. Dia. 4.3mm x (L) 8.5mm, 10mm, 11.5mm, 13mm, 15mm. Dia. 5.0mm x (L) 8.5mm, 10mm, 11.5mm, 13mm, 15mm. **Abutments** Diameter : 3.5mm~6mm Vertical High : 2.5mm~10mm

Indication for Use : Royal-Dent Eureka 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.
Royal-Dent Eureka Dental Implant System is for one and two stage surgical procedures. It's not for immediate load.

Technological Characteristics :

	Subject Device	Predicate Devices
Device Name	Royal-Dent Eureka Dental Implant System	GS System (K063861) GS III System (K091208)
Indication for use	Royal-Dent Eureka 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. Royal-Dent Eureka Dental Implant System is for one and two stage surgical procedures. It's not for immediate load.	GS System and GS III System are 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, abutments support for fixed bridgework. GS and GS III System is for one stage surgical procedures. It's not for immediate load.
Material(s)	CP Ti : dental implant Ti6Al4V: abutments, screws, healing caps, clix.	CP Ti: dental implant, cover screw, healing abutment. Ti6Al4V: abutments, screws, healing caps, clix. Gold alloy + plastic: casting abutment, cylinder.
Use	Single use	Single use
Dimension of Implants	Diameter: 3.5, 4.0, 4.3, 4.5, 5.0mm Length: 8.5, 10,11.5,13,15mm	Diameter: 3.5, 4.0,4.5, 5.0mm Length: 7.0,8.5,10,11.5,13,15mm
Method of sterilization	Gamma sterilization: implant Abutments and accessories : non-sterile	Gamma sterilization: implant Abutments and accessories : non-sterile

Performance Data : Pre-clinical testing of Royal-Dent Eureka Dental Implant System

- ◆ Bench testing per ISO 14801
- ◆ Genotoxicity Testing per ISO 10993-3
- ◆ Cytotoxicity testing per ISO 10993-5
- ◆ Implantation testing per ISO 10993-6
- ◆ Sensitization testing per ISO10993-10
- ◆ System Injection testing per ISO10993-11

Conclusion :

The comparisons of Royal-Dent Eureka Dental Implant System and predicate devices show that the devices are manufactured from same or similar materials, and have the same indication for use and similar design characteristics. Performance Testing were also conducted to demonstrate safety and effectiveness of the proposed devices. Based on the similarities between the Royal-Dent Eureka Dental Implant System and the predicate devices, the safety and effectiveness of the Royal-Dent Eureka Dental Implant System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 20, 2013

Mr. Kevin Wang
Regulatory Affairs Specialist
INTAI Technology Corporation
No.9, Jingke Road, Nantun District
Taichung City, Taiwan 40852

Re: K122804
Trade/Device Name: Royal-Dent Eureka Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 16, 2013
Received: May 16, 2013

Dear Mr. Wang:

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 contact 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. 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,

Kwame O. Ulmer-S for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122804

Device Name: **Royal-Dent Eureka Dental Implant System**

Indications for Use:

Royal-Dent Eureka 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.

Royal-Dent Eureka Dental Implant System is for one and two stage surgical procedures: It's not for immediate load.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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)

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner, 0.9.2342.19200300.100.1.1=1300087950
Date: 2013.05.20 12:09:36 -04'00'

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

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