K131468

GDT Green DenTech Co., Ltd
2F, No. 17, Deyuanpi Blvd., Da Nong Li, Liouying District, Tainan City, 73659, Taiwan.

MAY 0 6 2014

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 on May 06, 2014.

The assigned 510(k) number is: K131468

1. APPLICANT's NAME AND ADDRESS

Applicant' Name:	Green DenTech Co., Ltd
Address:	2F, No. 17, Deyuanpi Blvd., Da Nong Li, Liouying District, Tainan City, 73659, Taiwan.
Telephone:	886-6-6230999
Fax:	886-6-6230789
Official contact:	Henry H.J. Shih
Date Prepared:	May 06, 2014

2. DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Denracle Dental Abutment
Common Name:	Dental implant abutment
Classification Regulations:	Endosseous dental implant abutment Class II, 21 CFR 872.3630
Product Code:	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices

3. LEGALLY MARKETED DEVICES
TDS Abutment for Friadent Xive – K103339.

4. DEVICE DESCRIPTION
Denracle Dental Abutment for Osstem GS Implant are titanium abutments designed to be used in conjunction with specific dental implants utilizing the Denracle Dental Abutment screw, which is made of Ti-6A1-4V ELI titanium and is used to secure the abutment to the implant. In combination with the implant, the abutments support single or multi-unit cement-retained restorations in the maxillary and/or mandibular arch. Denracle Dental Abutment for Osstem GS Implant is compatible with the following implant systems: OSSTEM GS Fixture System Ø4.0 mm, Ø4.5 and Ø5.0mm.

5. INTENDED USE OF THE DEVICE
Denracle Dental Abutment for Osstem GS Implant is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

This device is compatible with the following implant system: OSSTEM GS Fixture System Ø 4.0 mm, Ø 4.5 mm and Ø 5.0 mm.

6. TECHNOLOGICAL CHARACTERISTICS

Denracle Dental Abutment for Osstem GS Implant has the following similarities to the predicate devices, TDS Abutment for Friadent Xive, which have been determined by FDA:

- Has the same intended use,
- Use the same operating principle,
- Incorporates the same basic design,
- Incorporates the same materials, and
- Is produced using the same processes.

The basis for Green DenTech Co., Ltd. Belief that TDS Abutment for Friadent Xive is substantially equivalent to the predicate devices is summarized in the following table.

	Predicate Devices	Subject Device
	Denracle Dental Abutment for Osstem GS implant	Pou Yu Biotechnology Co. TDS Abutment for Friadent Xive K103339
Intended use	Denracle Dental Abutment for Osstem GS Implant is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. Denracle Dental Abutment for Osstem GS Implant is compatible with the following implant system: OSSTEM GS Fixture System Ø 4.0 mm, Ø 4.5 mm and Ø 5.0 mm.	TDS Abutment for Friadent Xive is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. TDS Abutment for Friadent Xive is compatible with the following implant systems which have an internal hex 1.78mm or greater: Firadent: FRIALIT Implant, Xive Implant; 3i: Internal connect Type; Astra: Osseospeed Implant, Osseospeed TX Implant; BioHorizons: Internal Implant system, Tapered Internal Implant System, Single-Stange Implant System, Laser-lok 3.0 implant RENOVA ™ Internal Hex Implant System; Zimmer: Tapered Screw-Vent Implant System, Screw-Vent Implant System, AdVent Implant System; Osstem: GS system; Noble Biocare: Active Impalnt.
Custom Design		
Attachment	Implant level	Implant level
Restoration	Cement-retained	Cement-retained
CAD/CAM processing	Not CAD/CAM millable	Yes
Material		
Abutment	Ti-6A1-4V ELI	Ti-6A1-4V ELI Y-TZP Zinconia
Screw	Provided by Green Dentech Co., Ltd.	Provided by Pou Yu Biotechnology Co. Ltd.

7. NON-CLINICAL TESTING DATA

Mechanical testing, according to ISO 14801 Dentistry – Fatigue test for endosseous dental implants, was conducted on a worst-case scenario to ensure that the strength Denracle Dental Abutment for Osstem GS Implant is appropriate for its intended use.

Compatibility testing was conducted on the abutments and corresponding dental implants (which have had previous 510(K) clearance in K072896) with designated screws, the dimensions, tolerances and rotation parameters were evaluated in determining appropriate fit.

Biocompatibility testing and sterilization validation was performed on the device with acceptable results.

These testing results show that Denracle Dental Abutment for Osstem GS Implant made of titanium, for their respective dental implant system have sufficient mechanical strength for their intended clinical application and are compatible with the implant system for which they are indicated for use.

8. CONCLUSION

Green DenTech Co., Ltd demonstrated that, for the purposes of FDA's regulation of medical devices, GO series Denracle Dental Abutment for Osstem GS Implant is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment 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 6, 2014

Green DenTech Company Limited
Ms. Sue Ru
Official Correspondent
2F, No. 17, Deyuanpi Boulevard
Danung Li, Liouying District
Tainan 73659
TAIWAN

Re: K131468
Trade/Device Name: Denracle Dental Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 13, 2014
Received: March 24, 2014

Dear Ms. Ru:

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,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131468

Device Name
Denracle Dental abutment

Indications for Use *(Describe)*
Denracle Dental Abutment for OSSTEM GS Implant is intended for use with dental implant as a support for single or multiple tooth prostheses in maxilla or mandible of a partially or fully edentulous patient.
This device is compatible with the following implant system:OSSTEM GS Fixture System
ø4.0mm、ø4.5mm、ø5.0mm。

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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Food and Drug Administration

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