K091026

510(k) Summary
Pou Yu Biotechnology Co., Ltd
TDS Abutment for Nobel Biocare Replace

ADMINISTRATIVE INFORMATION

JUN 24 2009

Manufacturer Name: Pou Yu Biotechnology Co., Ltd.
No. 6 Fugong Rd.
Fusing Township
Changhua County 506, Taiwan
Telephone: +886-(0)4 768 5660 x5122
Fax: +886-(0)4 768 9032

Official Contact: Daniel Tsao

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	TDS Abutment for Nobel Biocare Replace
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 Branch

INTENDED USE

TDS Abutment for Nobel Biocare Replace 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.

DEVICE DESCRIPTION

TDS Abutment for Nobel Biocare Replace are titanium and ceramic-titanium abutments designed to be used in conjunction with specific dental implants utilizing the TDS Abutment screw, which is made of Ti-6A1-V 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. TDS Abutment for Nobel Biocare Replace are compatible with Nobel Replace® Select Straight, Nobel Replace Select Straight One Stage, Replace Select Tapered and Replace Select Tapered One Stage, Nobel Replace Straight, Nobel Replace Tapered, Nobel Replace Straight Groovy, and Nobel Replace Tapered Groovy for the 3.5 mm (NP), 4.3 mm (RP), 5.0 mm (WP) and 6.0 mm (WP) implants.

EQUIVALENCE TO MARKETED DEVICE

Pou Yu Biotechnology Co. Ltd demonstrated that, for the purposes of FDA's regulation of medical devices, TDS Abutment is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2009

Mr. Daniel Tsao
Manager
Pou Yu Biotechnology Company, Limited
No. 6, Fugong RD
Fusing Township Changhua City
China, Taiwan 506

Re: K091026
Trade/Device Name: TDS Abutment for Nobel Biocare Replace
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 7, 2009
Received: April 13, 2009

Dear Mr. Tsao:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting 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): K091026

Device Name: TDS Abutment for Nobel Biocare Replace

Indications for Use:

TDS Abutment for Nobel Biocare Replace 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 Nobel Biocare Replace is compatible with the following implant systems: Nobel Replace® Select Straight, Nobel Replace Select Straight One Stage, Replace Select Tapered and Replace Select Tapered One Stage, Nobel Replace Straight, Nobel Replace Tapered, Nobel Replace Straight Groovy, and Nobel Replace Tapered Groovy for the 3.5 mm (NP), 4.3 mm (RP), 5.0 mm (WP) and 6.0 mm (WP) implants.

Note: Highly angled abutments (i.e. 30°) on implants with diameters less than 4 mm are not intended for the posterior region of the mouth due to limited strength of the implant.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Betz DDS for Dr Kevin Mulay

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

Confidential

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