K091693

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

JUL 30 2009

ADMINISTRATIVE INFORMATION

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

DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Proprietary Name: | TDS Zirconia Abutment for Nobel Biocare Branemark, |
| Common Name: | Dental implant abutment |
| Classification Regulations: | Endosseous dental implant abutment<br>Class II, 21 CFR 872.3630 |
| Product Code: | NHA |
| Classification Panel: | Dental Products Panel |
| Reviewing Branch: | Dental Devices Branch |

## INTENDED USE

TDS Zirconia Abutment for Nobel Biocare Branemark 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 Zirconia Abutment for Nobel Biocare Branemark are zirconia abutments made of yttria-stabilized zircona (Y-TZP) designed to be used in conjunction with specific dental implants utilizing the TDS 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. TDS Zirconia Abutment for Nobel Biocare Branemark is compatible with the following implant systems which have an external hex with flat-to-flat dimensions of 2.4mm or greater: Nobel Biocare Branemark, 3i, BioHorizons, and Lifecore.

## EQUIVALENCE TO MARKETED DEVICE

Pou Yu Biotechnology Co. Ltd demonstrated that, for the purposes of FDA's regulation of medical devices, TDS Zirconia Abutment for Nobel Biocare Branemark 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

Mr. Daniel Tsao
Manager
Pou Yu Biotechnology Company, Limited
No. 6 Fugong Road
Fusing Township
Changhua County 506
TAIWAN

JUL 30 2009

Re: K091693
Trade/Device Name: TDS Zirconia Abutment for Nobel Biocare Branemark
Regulation Number: 21 CFR 872.3630
Regulation Name: Preformed Cusp
Regulatory Class: II
Product Code: NHA
Dated: June 5, 2009
Received: June 10, 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): _K091693_

Device Name: TDS Zirconia Abutment for Nobel Biocare Branemark

Indications for Use:

TDS Zirconia Abutment for Nobel Biocare Branemark 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 systems which have an external hex with flat-to-flat dimensions of 2.4mm or greater: **Nobel Biocare:** Branemark System® Mk III Groovy, Branemark System® Mk III Shorty, Branemark System® Zygoma, NobelSpeedy Groovy, NobelSpeedy Shorty; **3i:** Nano Tite External Hex Connection Implants, Full OSSEOTITE External Hex Connection Implants, OSSEOTITE External Hex Connection Implant; **BioHorizons:** Maestro - External Hex Implants; **Lifecore:** Restore External Hex Implant Systems.

| Prescription Use __X__ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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



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