K100356

510(k) Summary
Pou Yu Biotechnology Co., Ltd
TDS Precision Dental Bar

OCT - 5 2010

APPLICANT'S NAME AND ADDRESS

Applicant's Name:	Pou Yu Biotechnology Co., Ltd.
Address:	No. 6 Fugong Rd. Fusing Township
	Changhua County 506, Taiwan
Telephone:	+886-(0)4-768-5660 x5122
Fax:	+886-(0)4-768-9032
Contact person:	Daniel Tsao
Date Prepared:	February 2, 2010

NAME OF THE DEVICE

Trade/Proprietary Name:	TDS Precision Dental Bar
Common Name:	Dental implant bar
Classification Name:	Endosseous dental implant abutment
	Class II, 21 CFR 872.3630
Product Code:	NHA

LEGALLY MARKETED DEVICES

BIOMET 3i , Incorporated. - CAM StructSURE® Precision Milled Bars - K080864
Cagenix, Incorporated. - Accuframe TM - K081157
Nobel Biocare USA LLC. - NobelProcera Implant Bridge Zirconia - K091907

DESCRIPTION OF THE DEVICE

TDS Precision Dental Bars are prosthetic frameworks and made of machined titanium, zirconia-titanium, and zirconia materials. They are connected with dental implants utilizing the TDS screw which is made of Ti-6A1-4V ELI (Extra Low Interstitial) alloy. TDS Precision Dental Bars are

fabricated individually following instructions to each patient and serve to support and/or retain fixed dental prosthesis or removable dental prosthesis. They are compatible with dental implants manufactured by NobelBiocare, Camlog, BIOMET 3i, Zimmer, Lifecore, Astra, BioHorizons, Straumann, Dentsply Friadent, and Osstem.

INTENDED USE OF THE DEVICE

TDS Precision Dental Bars are indicated for use with dental implants as a prosthetic framework to support and/or retain removable or fixed dental prostheses in the treatment of partially or totally edentulous jaws to restore chewing function. The abutment screws are intended to secure the bar to the endosseous implants.

TDS Titanium Precision Dental Bars, made of machined titanium material, are compatible with following implant systems:

Implant brand	Model
NobelBiocare	Branemark - NP, RP, WP; Replace - NP, RP, WP, 6.0 mm; NobelActive - NP, RP
Camlog	3.8, 4.3, 5.0, 6.0 mm
BIOMET 3i	External - 3.4, 4.1, 5.0, 6.0 mm; Certain - 3.4, 4.1, 5.0, 6.0 mm
Zimmer	Tapered Screw-vent - 3.5, 4.5, 5.7 mm
Lifecore	External Hex - SD, RD, WD; Internal Hex - SDI 3.75, RDI 4.5/4.75 mm
Astra	OsseoSpeed - 3.5/4.0, 4.5/5.0 mm
BioHorizons	External - 3.5, 4.0, 5.0, 6.0 mm; Internal - 3.5, 4.5, 5.7 mm
Straumann	NN, RN, WN; Bone Level - NC 3.3, RC 4.1, RC 4.8 mm
Dentsply Friadent	XiVE - 3.0 mm; Frialit(XiVE) - 3.4, 3.8, 4.5, 5.5 mm; Frialit - 6.5 mm
Osstem	GS - Mini, Standard ; SS - Regular, Wide ; US - Mini, Regular, Wide

TDS Zirconia Precision Dental Bars, made of machined zirconia material, are compatible with following implant systems:

Implant brand	Model
NobelBiocare	Branemark - NP, RP, WP
BIOMET 3i	External - 3.4, 4.1, 5.0, 6.0 mm
Lifecore	External Hex - SD, RD, WD
BioHorizons	External - 3.5, 4.0, 5.0, 6.0 mm
Straumann	NN
Osstem	US - Mini, Regular, Wide

TDS Hybrid Precision Dental Bars, made of machined zirconia-titanium materials, are compatible with following implant systems:

Implant brand	Model
NobelBiocare	Replace - NP, RP, WP, 6.0 mm; NobelActive - NP, RP
Camlog	3.8, 4.3, 5.0, 6.0 mm
BIOMET 3i	Certain - 3.4, 4.1, 5.0, 6.0 mm
Zimmer	Tapered Screw-vent - 3.5, 4.5, 5.7 mm
Lifecore	Internal Hex - SDI 3.75, RDI 4.5/4.75 mm
Astra	OsseoSpeed - 3.5/4.0, 4.5/5.0 mm
BioHorizons	Internal - 3.5, 4.5, 5.7 mm
Straumann	RN, WN; Bone Level - NC 3.3, RC 4.1, RC 4.8 mm
Dentsply Friadent	XiVE - 3.0 mm; Frialit(XiVE) - 3.4, 3.8, 4.5, 5.5 mm; Frialit - 6.5 mm
Osstem	GS - Mini, Standard ; SS - Regular, Wide

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.

TECHNOLOGICAL CHARACTERISTICS

The TDS Precision Dental Bar has the following similarities to the predicate devices which have been determined by FDA:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- is produced using the same processes.

NON-CLINICAL TESTING DATA

Mechanical testing, according to ISO 14801 *Dentistry - Fatigue test for endosseous dental implants,* was conducted on a worst-case scenario with construction of an angle abutment to ensure that the strength of the abutment for TDS Precision Dental Bar is appropriate for its intended use. Compatibility testing was conducted on the abutments and corresponding dental implants with designated screws, the dimensions, tolerances and rotation parameters were evaluated in determining

appropriate fit.

These testing results show that TDS Precision Dental Bar made of titanium, zirconia-titanium and zirconia materials for their respective dental implant systems have sufficient mechanical strength for their intended clinical application and are compatible with the implant systems for which they are indicated for use.

BASIS FOR SUBSTANTIAL EQUIVALENCE

Pou Yu Biotechnology Co. Ltd demonstrated that, for the purposes of FDA's regulation of medical devices, TDS Precision Dental Bar is substantially equivalent in intended use, materials, design principles and produced processes 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Daniel Tsao
Manager
Pou Yu Biotechnology Company, Limited
No. 6 Fugong Road
Fusing Township, Changhua City
CHINA (Taiwan) 506

OCT - 5 2010

Re: K100356
Trade/Device Name: TDS Precision Dental Bar
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: September 3, 2010
Received: September 9, 2010

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. 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 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/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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K100356

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Device Name: TDS Precision Dental Bar

Indications for Use:

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Osstem	GS - Mini, Standard ; SS - Regular, Wide ; US - Mini, Regular, Wide

TDS Zirconia Precision Dental Bars, made of machined zirconia material, are compatible with following implant systems:

Implant brand	Model
NobelBiocare	Branemark - NP, RP, WP
BIOMET 3i	External - 3.4, 4.1, 5.0, 6.0 mm
Lifecore	External Hex - SD, RD, WD
BioHorizons	External - 3.5, 4.0, 5.0, 6.0 mm
Straumann	NN
Osstem	US - Mini, Regular, Wide

TDS Hybrid Precision Dental Bars, made of machined zirconia-titanium materials, are compatible with following implant systems:

Implant brand	Model
NobelBiocare	Replace - NP, RP, WP, 6.0 mm; NobelActive - NP, RP
Camlog	3.8, 4.3, 5.0, 6.0 mm
BIOMET 3i	Certain - 3.4, 4.1, 5.0, 6.0 mm
Zimmer	Tapered Screw-vent - 3.5, 4.5, 5.7 mm
Lifecore	Internal Hex - SDI 3.75, RDI 4.5/4.75 mm
Astra	OsseoSpeed - 3.5/4.0, 4.5/5.0 mm
BioHorizons	Internal - 3.5, 4.5, 5.7 mm
Straumann	RN, WN; Bone Level - NC 3.3, RC 4.1, RC 4.8 mm
Dentsply Friadent	XiVE - 3.0 mm; Frialit(XiVE) - 3.4, 3.8, 4.5, 5.5 mm; Frialit - 6.5 mm
Osstem	GS - Mini, Standard ; SS - Regular, Wide

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__ 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K100356