510(k) Summary
Pou Yu Biotechnology Co., Ltd
TDS Abutment for Friadent Xive

MAR 3 1 2011

APPLICANT'S NAME AND ADDRESS

Applicant' Name:	Pou Yu Biotechnology Co., Ltd.
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Official Contact:	Daniel Tsao
Date Prepared:	November 5, 2010

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	TDS Abutment for Friadent Xive,
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

LEGALLY MARKETED DEVICES

FRIADENT GmbH. – Xive TG Abutments –K032302
Lifecore Biomedical Inc. – PrimaConnex® CAD/CAM Abutment System- K072241
Atlantis Components, Inc. – Atlantis™ Abutment in Zirconia for 3i Certain Interface- K063734.

DEVICE DESCRIPTION

TDS Abutment for Friadent Xive 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-6A1-4V 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 Abutment for Friadent Xive is compatible with the following implant systems which have an internal hex with flat-to-flat dimensions of 1.78mm or greater: **Firadent:** FRIALIT Implant, XiVA Implant; **3i:** Internal Connect Type; **Astra:** Osseospeed Implant, Osseospeed TX Implant; **BirHorizons:** Internal Implant System, Tapered Internal Implant System, Single-Stage Implant System, Laser-lok® 3.0 implant system; **Lifecore:** Lifecore RENOVA™ Internal Hex Implant System; **Zimmer:** Tapered Screw-Vent Implant System, Screw-Vent Implant System, AdVent Implant System; **Osstem:** GS System; **Nobel Biocare:** Active Impalnt.

INTENDED USE OF THE DEVICE

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.

This device is compatible with the following implant systems which have an internal hex with flat-to-flat dimensions of 1.78mm or greater: **Firadent:** FRIALIT Implant, XiVA Implant; **3i:** Internal Connect Type; **Astra:** Osseospeed Implant, Osseospeed TX Implant; **BioHorizons:** Internal Implant System, Tapered Internal Implant System, Single-Stage Implant System, Laser-lok® 3.0 implant system; **Lifecore:** Lifecore RENOVA™ Internal Hex Implant System; **Zimmer:** Tapered Screw-Vent Implant System, Screw-Vent Implant System, AdVent Implant System; **Osstem:** GS System; **Nobel Biocare:** Active Implant.

TECHNOLOGICAL CHARACTERISTICS

TDS Abutment for Friadent Xive 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.

The basis for Pou Yu Biotechnology Co. Ltd.'s belief that TDS Abutment for Friadent Xive is substantially equivalent to the predicate devices is summarized in the following table.

	Subject Device	Predicate Devices		
	Pou Yu Biotechnology Co. TDS Abutment for Friadent Xive	FRIADENT GmbH. XiVE TG Abutments K032302	Lifecore Biomedical Inc. PrimaConnex® CAD/CAM Abutment System K072241	Atlantis Components, Inc. Atlantis™ Abutment in Zirconia for 3i Certain Interface K063734
Intended use	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 with flat-to-flat dimensions of 1.78mm or greater: **Firadent:** FRIALIT Implant, XiVA Implant; 3i: Internal Connect Type; **Astra:** Osseospeed Implant, Osseospeed TX Implant; **BioHorizons:** Internal Implant System, Tapered Internal Implant System, Single-Stage Implant System, Laser-lok® 3.0 implant system; **Lifecore:** Lifecore RENOVA™ Internal Hex Implant System; **Zimmer:** Tapered Screw-Vent Implant System, Screw-Vent Implant System, AdVent Implant System; **Osstem:** GS System; **Nobel Biocare:** Active Impalnt.	The XiVE TG Abutment is intended for use in the fabrication of screw-retained and cementable crowns and bridges.	The Lifecore PrimaConnex® CAD/CAM Abutment System is intended for use as an accessory to a Lifecore PrimaConnex endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The copings are intended for use as a core structure for a prosthetic restoration in partially or fully edentulous mandibles or maxillae in the construction of single-unit cement retained restorations on Lifecore PrimaConnex CAD/CAM Abutments.	The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic reconstruction. The Atlantis Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis,.in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. Please note: Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to the limited strength of the implant fixture.
Custom Design				
Attachment	Implant level	Implant level	Implant level	Implant level
Restoration	Cement-retained	Cement-retained	Cement-retained	Cement-retained
CAD/CAM processing	Yes	Yes	Yes	Yes
Material				
Abutment	Ti-6Al-4V ELI ; Y-TZP Zirconia	Ti-6Al-4V ELI	Y-TZP Zirconia	Y-TZP Zirconia
Screw	Provided by Pou Yu Biotechnology Co. Ltd.	Provided by individual manufacturers for specified implants	Provided by individual manufacturers for specified implants	Provided by Atlantis Components, Inc.

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 TDS Abutment for Friadent Xive 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 Abutment for Friadent Xive 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.

CONCLUSION

Pou Yu Biotechnology Co. Ltd demonstrated that, for the purposes of FDA's regulation of medical devices, TDS Abutment for Friadent Xive 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 Room –WO66-G609
Silver Spring, MD 20993-0002

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

MAR 3 1 2011

Re: K103339
Trade/Device Name: TDS Abutment for Friadent Xive
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: March 17, 2011
Received: March 17, 2011

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): K103339

Device Name: TDS Abutment for Friadent Xive

Indications for Use:

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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)

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

510(k) Number: K103339