K121178

510(k) Summary

National Dentex Corporation

NDX Custom Abutments

DEC 14 2012

December 13, 2012

ADMINISTRATIVE INFORMATION

Manufacturer Name:	National Dentex Corporation 2 Vision Drive Natick, MA 01760 Telephone: +1 (508) 907-7800 Fax: +1 (508) 907-6050
Official Contact:	Dell Dine
Representative/Consultant:	Linda Schulz or Kevin Thomas PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: lschulz@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	NDX Custom Abutments
Classification Name:	Abutment, Implant, Dental, Endosseous
Classification Regulations:	Endosseous dental implant 21 CFR 872.3630, Class II
Product Code:	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

NDX Custom Abutments are 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.

NDX Abutment for Nobel Biocare Brånemark is compatible with the following implant systems:

Nobel Biocare:	Brånemark System® Mk III Groovy
	Brånemark System® Mk III Shorty
	Brånemark System® Zygoma
	NobelSpeedy Groovy
	NobelSpeedy Shorty

NDX Abutment for Nobel Biocare Replace is compatible with the following implant systems:

Nobel Biocare:	Nobel Replace® Select Straight
	Nobel Replace Select Straight One Stage
	Replace Select Tapered
	Replace Select Tapered One Stage
	Nobel Replace Straight
	Nobel Replace Tapered
	Nobel Replace Straight Groovy
	Nobel Replace Tapered Groovy for the 3.5 mm (NP)
	4.3 mm (RP), 5.0 mm (WP) and 6.0 mm implants

NDX Abutment for Nobel Active is compatible with the following implant system:

Nobel Biocare:	NobelActive Implant

NDX Abutment for 3i External Hex is compatible with the following implant systems:

3i:	NanoTite External Hex Connection Implants
	Full OSSEOTITE External Hex Connection Implants
	OSSEOTITE External Hex Connection Implant

NDX Abutment for 3i Certain Internal is compatible with the following implant system:

3i:	Certain Internal Connection

DEVICE DESCRIPTION

NDX Custom Abutments are fabricated for a specific prosthetic case and implant interface using a Computer Assisted Design /Computer Assisted Manufacturing (CAD/CAM) scanning and milling process. Milling of NDX Custom Abutments includes anti-rotation features compatible with specific implant systems. Each abutment is made from titanium alloy. It is created according to the specific design parameters designated by the clinician. All components and parameters of the system remain identical to those cleared for the TDS Abutment System predicates. Abutments are available in diameters of 3.5, 4.1, 4.3, 5.0, 5.1, and 6.0 mm, and can be fabricated straight or with an angle up to 30°.

EQUIVALENCE TO MARKETED DEVICE

National Dentex submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, NDX Custom Abutments is substantially equivalent in indications and design principles to the following predicate devices, all manufactured by Pou Yu Biotechnology Co., Ltd.:

TDS Abutment for Friadent Xive - K103339,
TDS Titanium Abutment for Nobel Biocare Brånemark - K091392,
TDS Abutment for Nobel Biocare Replace - K091026, and
TDS Abutment - K081460

The purpose of this submission is to give National Dentex Corporation the ability to utilize the currently cleared TDS CAD/CAM Abutment System for dental implant abutment fabrication. All component designs and parameters of the system remain identical to those previously cleared for the TDS CAD/CAM Abutment System.

Mechanical testing was conducted on worst-case constructs of NDX titanium abutments according to ISO 14801 *Dentistry - Implants - Dynamic fatigue test for endosseous dental implants* and results showed adequate strength for their intended use. Extensive compatibility testing was performed in support of NDX Abutments. Multiple parameters of the NDX abutments and corresponding implants with designated screws were evaluated to determine appropriate fit.

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: engineering analysis, dimensional analysis, static and dynamic compression-bending testing according to ISO 14801, and sterilization validation according to ISO 17665.

The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, NDX Custom Abutments have the following similarities to the predicate devices:

- have the same intended use,
- use the same operating principle,
- incorporate the same design,
- incorporate the same materials, and
- have similar packaging and are sterilized using the same materials and processes.

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

December 14, 2012

National Dentex Corporation
C/O Ms. Linda K. Schulz
PaxMed International, Limited Liability Company
12264 El Camino Real, Suite 400
SAN DIEGO CA 92130

Re: K121117
Trade/Device Name: NDX Custom Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 3, 2012
Received: December 5, 2012

Dear Ms. Schulz:

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,

Susan Runner DDS, MA 2012.12.14 14:09:38 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K121117

Device Name: NDX Custom Abutments

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3i: NanoTite External Hex Connection Implants
Full OSSEOTITE External Hex Connection Implants
OSSEOTITE External Hex Connection Implant

NDX Abutment for 3i Certain Internal is compatible with the following implant system:
3i: Certain Internal Connection

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.12.14 14:08:29 -05'00'

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

510(k) Number: _____