K083543

510(k) Summary

MAR 6 2009

Denovis Medical, LLC
DenovisMed Dental Implant System

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Denovis Medical, LLC 1121 N. Bethlehem Pike, Suite 60-104 Spring House, Pennsylvania 19477, USA Telephone: +1 (215) 654-0177 Fax: +1 (215) 654-0178
Official Contact:	Roger Ranck Denovis Medical, LLC Telephone: +1 (215) 654-0177 Fax: +1 (215) 654-0178 email: rranck@denovismed.com
Representative/Consultant:	Kevin A. Thomas Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 email: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	DenovisMed Dental Implant System
Common Name:	Dental implant; Dental implant abutment
Classification Regulations:	Implant, endosseous, root-form; Endosseous dental implant abutment 21 CFR 872.3640, 21 CFR 872.3630 Class II
Product Codes	DZE; NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

For immediate or delayed placement and function on single-tooth and/or multiple tooth applications in the maxillary and or mandibular arches to support crowns, bridges, and overdentures in edentulous or partially edentulous patients. Immediate loading is indicated for single tooth and/or multiple tooth applications when there is good primary stability and an appropriate occlusal load.

DEVICE DESCRIPTION

The DenovisMed Dental Implant System is intended to support prosthetic devices in edentulous or partially edentulous patients to restore esthetics and chewing function. The System consists of the DenovisMed Dental Implant, a self-tapping, threaded, root-formed dental implant as well as straight abutments and related prosthetic components.

EQUIVALENCE TO MARKETED DEVICE

Denovis Medical, LLC demonstrated that, for the purposes of FDA's regulation of medical devices, the DenovisMed Dental Implant System 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. Overall, the DenovisMed Dental Implant System has the following similarities to the predicate devices:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2009

Denovis Medical, LLC
C/o Kevin A. Thomas, Ph.D.
Senior Regulatory Specialist
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K083543
Trade/Device Name: DenovisMed Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: February 11, 2009
Received: February 12, 2009

Dear Dr. Thomas:

This letter corrects our substantially equivalent letter of March 6, 2009.

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 (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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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, DDS, MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K083543

510(k) Premarket Notification DenovisMed Dental Implant System

Indications for Use

510(k) Number (if known): K083543

Device Name: DenovisMed Dental Implant System

Indications for Use:

For immediate or delayed placement and function on single-tooth and/or multiple tooth applications in the maxillary and or mandibular arches to support crowns, bridges, and overdentures in edentulous or partially edentulous patients. Immediate loading is indicated for single tooth and/or multiple tooth applications when there is good primary stability and an appropriate occlusal load.

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)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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