

510(k) Summary

OCT 23 2007

Olympus Dental Implant System

ADMINISTRATIVE INFORMATION

Manufacturer Name: Keystone Dental, Inc.
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Burlington, MA 01803
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Fax 1 (781) 272-9972

Official Contact: Linda Jalbert

Representative/Consultant: Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: Olympus Dental Implant System
Common Name: dental implants and abutments
Classification Regulations: Endosseous dental implant
(21 CFR 872.3640), Class II
Endosseous dental implant abutment
(21 CFR 872.3630), Class II

Product Codes DZE, NHA

DEVICE CLASSIFICATION PANEL

The Classification Panel for these devices is the Dental Products Panel, and they are reviewed by the Dental Devices Branch.

INTENDED USE

The Olympus Dental Implant System is intended to be surgically placed, either immediately after extraction or following healing, in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. Olympus Dental Implants with an insertion depth of 8 mm or more can be loaded immediately if they have achieved adequate primary stability.

DEVICE DESCRIPTION

The Olympus Dental Implant System includes various sizes of parallel sided, threaded, root-form dental implants and straight abutments intended to support prosthetic restorations in edentulous or partially edentulous patients. The implants can be placed immediately following extraction or after a healing period. If good primary stability is reached according to the Instructions for Use, Olympus Dental Implants with an insertion depth of 8 mm or more may be immediately loaded. The system includes a variety of laboratory (burnout) copings, impression copings, analogs and other components (Class 1 exempt, not a subject of this submission) intended to facilitate the preparation of prosthetic restorations.

EQUIVALENCE TO MARKETED PRODUCT

Keystone Dental, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the Olympus 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2007

Keystone Dental, Incorporated
C/O Mr. Floyd G. Larson
President
PaxMed International, LLC
11234 EL Camino Real Suite 200
San Diego, California 92130

Re: K071070
Trade/Device Name: Olympus Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 1, 2007
Received: October 2, 2007

Dear Mr. Larson:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D. *CL*

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): **K071070**

Device Name: Olympus Dental Implant System

Indications for Use:

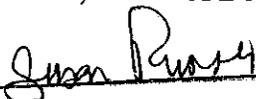
The Olympus Dental Implant System is intended to be surgically placed, either immediately after extraction or following healing, in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. Olympus Dental Implants with an insertion depth of 8 mm or more can be loaded immediately if they have achieved adequate primary stability.

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)



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

510(k) Number: K071070