

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Osteogenics Biomedical, Inc
3234 64th Street
Lubbock, TX 79413
(806) 792-2311

Contact Person: Chad Bartee

Date of Preparation: November 24, 1998

II. DEVICE NAME

Proprietary Name: Osteo-Mesh™ TM-300

Common Name: Titanium Ridge Augmentation Mesh

Classification Name: Bone Plate

III. PREDICATE DEVICE

OsteoMed TRAM™ (Titanium Ridge Augmentation Material); K963394;
OsteoMed Corporation.

IV. DEVICE DESCRIPTION

The Osteo-Mesh™ TM-300 titanium ridge augmentation mesh is fabricated from Grade 1 titanium as described by ASTM-F-67 or its ISO equivalent. The Osteo-Mesh™ TM-300 is supplied nonsterile in two sizes: 25 mm x 30 mm and 12 mm x 25 mm.

The biocompatibility of titanium has been established through a long history of use in a variety of implant devices. No additional biocompatibility testing has been performed with this device.

V. INTENDED USE

For stabilization and support of bone grafts in dento-alveolar bony defect sites.

VI. COMPARISON TO PREDICATE DEVICES

The Osteo-Mesh™ TM-300 is similar in composition, function, and intended use to legally marketed predicate devices, such as the OsteoMed TRAM™ (Titanium Ridge Augmentation Material).

Accordingly, Osteogenics Biomedical Inc. concluded that the Osteo-Mesh™ TM-300 is safe and effective for its intended use and performs at least as well as legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 1999

Osteogenics Biomedical, Incorporated
C/O Mr. Richard A. Hamer
Regulatory Consultant
Richard Hamer Associates, Incorporated
P.O.Box 16598
Fort Worth, Texas 76162-0598

Re: K984230
Trade Name: Osteo-Mesh TM-300
Regulatory Class: II
Product Code: JEY
Dated: November 24, 1998
Received: November 25, 1998

Dear Mr. Hamer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

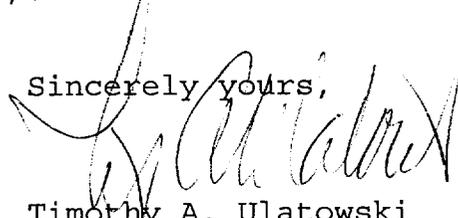
Page 2 - Mr. Hamer

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Osteo - Mesh™ TM-300
Titanium Ridge Augmentation Mesh

Indications for Use:

For stabilization and support of bone grafts in dento-alveolar bony defect sites.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)

Susan Purves
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 1K984030