K972278

AUG - 6 1997

510 (k) SUMMARY

I. ADMINISTRATIVE

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

Contact Person: Barry K. Bartee, DDS

Date of Preparation: June 2, 1997

II. DEVICE NAME

Proprietary Name: Cytoplast™ Regentex Titanium 250

Common Name: Non-Absorbable Barrier Membrane

Classification Name: Implant, Endosseous For Bone Filling And/Or Augmentation.

III. PREDICATE DEVICES

Gore-Tex™ Regenerative Material (K960292; W.L Gore & Associates, Inc.)
Cytoplast™ GBR Membrane (K964342; Osteogenics Co.)

IV. DEVICE DESCRIPTION

The Cytoplast™ Regentex Titanium 250 Non-Absorbable Barrier Membrane is composed of nanoporous high density polytetrafluoroethylene (n-PTFE) film reinforced with a titanium framework. The membrane has a nominal thickness of 250 microns. Membranes are supplied sterile in sealed pouches.in a variety of shapes and sizes.

The biocompatibility of polytetrafluoroethylene (PTFE) and titanium has been established through a long history of use in a variety of implant devices. No additional biocompatibility testing has been conducted with this device.

V. INTENDED USE

A temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal defects.

VI. COMPARISON TO PREDICATE DEVICES

The Cytoplast™ Regentex Titanium 250 Non-Absorbable Barrier Membrane is identical in composition, function, and intended use to legally marketed predicate devices such as Gore-Tex™ Regenerative Material. Except for the presence of a reinforcing titanium framework, the Cytoplast™ Regentex Titanium 250 Non-Absorbable Barrier Membrane is also identical in composition, function, and intended use to the legally marketed predicate Cytoplast™ GBR membrane.

Accordingly, Osteogenics Co. concluded that the Cytoplast™ Regentex Titanium 250 Non-Absorbable Barrier Membrane is safe and effective for its intended use and performs at least as well as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Osteogenics Company
C/O Richard Hamer Associates, Incorporated
6401 Meadows West Drive
Fort Worth, Texas 76132

AUG - 6 1997

Re: K972278
Trade Name: Cytoplast Regentex Titanium 250
Regulatory Class: Unclassified
Product Code: LYC
Dated: June 17, 1997
Received: June 18, 1997

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 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 (Premarket 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 requirement, 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: this response to your premarket notification submission does not affect any obligation you might have under sections 531 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) 594-4618. 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" (21 CFR 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/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

Enclosed

510(k) Number (if known): K972278

Device Name: Cytoplast™ Regentex Titanium 250 Non-Absorbable Barrier Membrane

Indications for Use:

A temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal bone defects.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K972278

Prescription Use Yes (Per 21 CFR 801.109) OR Over-the Counter Use No

(Optional Format 1-2-96)