K021511

AUG 0 6 2002

510(K) Summary

(As Required by Section 807.92 (c))

1. Submitter

Name:	Unicare Biomedical
Address:	25951 La Cuesta Avenue, Laguna Hills, CA 92653
Contact:	Stan Yang, 949-643-6707
Date:	February 20, 2002

2. Device Name

Trade Name:	Cytoflex Mesh
Common Name:	Precision Titanium Mesh
Classification Name:	Implant, Endosseous for bone filling and/or augmentation
Device Classification:	Unclassified

3. Predicate Devices

Precision Titanium Foil (Imtec Corporation)
Osteomed MSS (Osteomed Corporation)
Micro-Titanium Augmentation Mesh (Howmedica-Leibinger)
Ti Mini Bone Plate and Screws (Walter Lorenz Surgical, Inc.)
Reconstructive Surgery System (Ti Mesh Inc.)
Osteogenics Cytoplast GBR (Osteogenics Corporation)
Imtec BioBarrier membrane (Imtec Corporation)
Gore-tex Regenerative Material (W.L. Gore & Associates, Inc.)

4. Device Description

Cytoflex Mesh is a precision titanium mesh of a specific dimension and pore size. Cytoflex Mesh is supplied in specific sizes and thickness in sealed pouches. Cytoflex Mesh is tested, evaluated and found to be substantially equivalent to legally marketed predicate devices.

5. Indication

Cytoflex Mesh is indicated for use in ensuring three-dimensional reconstruction of alveolar bone defects and for facilitating augmentation with adequate fixation of the augmentation material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

Stan Yang, Ph.D.
Vice President of Operations
Unicare Biomedical, Incorporated
25951 La Cuesta Avenue
Laguna Hills, California 92653

Re: K021511
Trade/Device Name: Cytoflex Mesh
Regulation Number: 21 CFR 872.4760
Regulation Name: Precision Titanium Mesh
Regulatory Class: II
Product Code: JEY
Dated: May 3, 2002
Received: May 9, 2002

Dear Dr. Yang:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely,

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

Enclosure

510 (K) NUMBER (IF KNOWN): K021511

DEVICE NAME: CYTOFLEX™ MESH

INDICATIONS FOR USE:

For use to ensure three-dimensional reconstruction of alveolar bone defects and to facilitate augmentation with adequate fixation of the augmentation material.

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

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription of Use ✓ or Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)

Susan Runm

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

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