K09 0083

SECTION 5 - 510(k) Summary or 510(k) Statement

MAR 2 3 2009

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:	January 7, 2009

2. Device Name

Trade Name:	CytoFlex® Resorb
Common Name:	Absorbable barrier membrane
Classification Name:	Barrier, synthetic, intraoral
Device Classification:	II

3. Predicate Devices

Gore Resolut (K973594; W.L. Gore & Associates)
Biomesh (K990363; SamYang Corporation)
Bioscaff Alvelac (K080308; Bioscaffold International)

4. Device Description

CytoFlex® Resorb barriers are made from polyglycolide, polylactide and poly(glycolide-co-lactide) copolymer. CytoFlex® Resorb is a resorbable barrier membrane and is supplied in a variety of shapes and sizes in sealed pouches. CytoFlex® Resorb membrane is tested, evaluated and found to be substantially equivalent to legally marketed predicate devices.

5. Indication

CytoFlex® Resorb membranes are intended for use as a space-making barrier in the treatment of periodontal defects and maxillofacial guided tissue regeneration procedures, including preservation and regeneration of alveolar bone height and volume, ridge and extraction site augmentation, sinus lifts, and treatment of associated cystic defects. It is also intended for use as a grafting material containment matrix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2009

Mr. Stan Yang
Vice President
Unicare Biomedical, Incorporated
22971Triton Way, Unit B
Laguna Hills, California 92653

Re: K090083
Trade/Device Name: CytoFlex® Resorb
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: January 7, 2009
Received: January 12, 2009

Dear Mr. 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), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Ginette Y. Michaud M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: CytoFlex® Resorb

Indications for Use:

CytoFlex® Resorb membranes are intended for use as a space-making barrier in the treatment of periodontal defects and maxillofacial guided tissue regeneration procedures, including preservation and regeneration of alveolar bone height and volume, ridge and extraction site augmentation, sinus lifts, and treatment of associated cystic defects. It is also intended for use as a grafting material containment matrix.

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 OF NEEDED)

Susan Runner

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

510(k) Number: K040083