JAN 2 4 2001

K994060

BIOMEDICS, INC.
6911 Melrose Avenue
Los Angeles, California 90038
Tel: (323) 549-9500, FAX: (323) 935-0110

510(k) SUMMARY

The Bioplate® Resorbable Bone Plating System for Craniomaxillofacial Surgery consists of a variety of plate, mesh, and screw configurations intended for use in the treatment of fractures and reconstructive procedures of the craniomaxillofacial skeleton in which bioresorbable fixation is desired. Plates, mesh and screws are used to align and stabilize fractures of bony tissue while normal tissue healing occurs.

The plates, mesh, and screws are manufactured of a bioresorbable Poly(L-lactide) copolymer which resorbs by hydrolysis into lactic acids that are metabolized by the body. The material is substantially equivalent to that currently being used in fixation devices and is, in some cases, the exact same copolymer material.

Bioplate® resorbable plates, mesh, and screws are provided sterile by gamma radiation and must not be resterilized.

The substantial equivalence of this device is demonstrated by its similarity in intended use, design, dimensions, and materials to the **LactoSorb® Trauma Plating System (K955729)**, which is manufactured from 82:18 poly(L-lactide-co-glycolide)., the **Synthes (U.S.A.) Resorbable Fixation System (K974554)**, which is manufactured from 70:30 poly(L/DL-lactide), and the **Howmedica Leibinger Resorbable Fixation System (K982531)**, manufactured of material described in the 510(k) as "substantially equivalent to that used in the LactoSorb Device".

The device is also substantially equivalent in its intended use and design to the **Bioplate® Rigid fixation Bone Plating System for Craniomaxillofacial Surgery (K980983),** which is manufactured of non-resorbable titanium.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Eric V. Hohenstein
Engineering & Product Development Manager
Bioplate, Incorporated
6911 Melrose Avenue
Los Angeles, California 90038

Re: K994060
Trade Name: The Bioplate® Resorbable Bone Plating System for Craniomaxillofacial Surgery, Biolactate™
Regulatory Class: II
Product Code: JEY
Dated: October 24, 2000
Received: October 26, 2000

Dear Mr. Hohenstein:

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 (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 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: 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) 594-4692. 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): K994060

DEVICE NAME:

The Bioplate Resorbable Bone Plating System for Craniomaxillofacial Surgery

INDICATIONS FOR USE:

The Bioplate Resorbable Bone Plating System is intended for use in conjunction with the Bioplate Rigid Fixation Bone Plating System for craniomaxillofacial indications in which resorbable fixation is desired. Plates and screws are used to align and stabilize fractures of bony tissue while normal tissue healing occurs.

The resorbable plates and screws are intended for minimally load bearing fixation for the following indications:

- Craniofacial fractures
- Reconstructive procedures of the craniomaxillofacial skeleton
- Cranial bone fixation
- Brow lift procedures

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

CONCURRANCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use_____ (Optimal Format 1-2-96)

Gerald W Shipley for MSR

Division Sign-Off

510(k) Number K994060