JUL 27 2005 K051845

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's name, address, telephone number and contact person:

Bioplate, Inc.
3643 Lenawee Avenue
Los Angeles, CA, 90016
(310) 815-2100
(310) 815-2126 (fax)

Contact Person: Jesus Farinas

Trade name of Device:

Bioplate Resorbable Tack for craniomaxillofacial surgery.

Common Name:

Absorbable Bone Screw

Device Classification:

Class 2, 21 CFR 888.3040

Predicate Devices:

(1.) Bioplate, Inc.
The Bioplate Resorbable Bone Plating System
For Craniomaxillofacial Surgery, Biolactate ™
(K996040)

(2.) Bioplate, Inc.
The Bioplate Resorbable Bone Screw
(K012908)

K051845

Description of the Device:

The Bioplate Resorbable Bone Tack consists of a bone fixation device manufactured from a Poly (L-lactide-co-DL-lactide) co-polymer that has been implanted safely for a number of years. The bone fixation devices will be provided sterile to the end-user, using gamma radiation as the method of sterilization and are not intended for re-sterilized by the end-user.

Intended Use of the Device:

The Bioplate Resorbable Bone Fixation Tack will be used to support non-load bearing tissues of the craniomaxillofacial anatomy, including but not limited to brow fixation. Each device is intended for single use only.

Comparison of the device's technological characteristics with those of the predicate devices

The Bioplate Resorbable Tack, for use in the support of non-load bearing tissues of the craniomaxillofacial anatomy, including but not limited to brow fixation has some minor modifications to the Indications for Use; but has become more restrictive than the Indications for Use as the Bioplate (K994060) and (K012908). All of the technical characteristics are substantially equivalent to the corresponding characteristics of the predicate devices, and any minor differences raise no new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2005

Bioplate, Incorporated
c/o Mr. Jesus T. Farinas
3643 Lenawee Avenue
Los Angeles, California 90016-4310

Re: K051845
Trade/Device Name: The Bioplate Resorbable Endobrow Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone plate
Regulatory Class: II
Product Code: JEY
Dated: June 28, 2005
Received: July 7, 2005

Dear Mr. Farinas:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATION FOR USE

510(k) Number (if known): K051845

DEVICE NAME: Bioplate Resorbable Bone Fixation Tack

INDICATIONS FOR USE:

The Bioplate Resorbable Bone Fixation Tack will be used to support non-load bearing tissues of the craniomaxillofacial anatomy, including but not limited to brow fixation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Division Sign-Off

510(K) Number K051845

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

510(k) Number: K051845