K023810

Summary of Safety and Effectiveness

DEC 0 4 2002

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

Bioplate, Inc.
6911 Melrose Avenue
Los Angeles, CA 90038
(323) 549-9500
(323) 935-0110 (fax)

Contact Person: Judy Sokua

Trade Name of Device

Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery

Common name

Bone Plates

Classification name

Bone Plate (21 CFR 872.4760)

Predicate Devices

(1) Bioplate, Inc.
Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery
K021684

(2) Bioplate, Inc.
Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery
K980983

(3) Bioplate, Inc.
Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery
K972463

(4) Bioplate, Inc.
Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery
K953273

(5) Bioplate, Inc.
Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery
K943071

Description of the device

The modified plate designs for use in conjunction with the Bioplate Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery includes a variety of plate configurations for different anatomical applications. Commercially pure titanium plates, and titanium alloy screws of varying lengths are included for fixation of the plates to the craniomaxilloffacial bony tissue

The bone plates will be manufactured of commercially pure titanium (Grade 4). The materials adhere to the American Society of Testing and Materials (A.S.T.M) F67 Standards

Intended used of the device

The Bioplate Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery is intended for use in the treatment of craniofacial fractures, reconstructive procedures, and non-load bearing fixation including, maxillofacial fixation, cranial bone fixation and orbital fixation. Each device is intended for single use only and only in conjunction with other titanium and titanium alloy implants.

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

The modified plate design for use with the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial surgery has the same indications for use as the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery (K021684, K980983, K972463, K953273, and K943071) predicate devices. 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

DEC 0 4 2002

Ms. Judy Sokua
Regulatory Affairs Associate
Bioplate, Incorporated
6911 Melrose Avenue
Los Angeles, California 90038-3305

Re: K023810
Trade/Device Name: Modified Plate designed for use with the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: November 14, 2002
Received: November 15, 2002

Dear Ms. Sokua:

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 (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 yours,

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): K023810

Device Name: Modified plate designs for use with the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery

Indications for Use:

The modified plates designs for use with the Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery are intended for use in the treatment of fractures and reconstructive procedures of the craniomaxillofacial skeleton and non-weight bearing fixation, including cranial bone fixation, brow fixation and orbital fixation. Each device is intended for single use only and only in conjunction with other titanium and titanium alloy implants.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Susan Runner

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

510(k) Number K023810