APR 0 8 2003

K030806

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: Carol E. Jones

Trade Name of Device

The Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery

Common name

Bone plates and bone screws

Classification name

Bone Plate (21 CFR 872.4760)

Predicate Devices

(1) Walter Lorenz Surgical Instruments, Inc.
Lorenz Self Drilling Screw
K013954

(2) Synthes (USA)
Self Drilling Screw
K983485

(3) KLS-Martin L.P.
Centre-Drive Drill Free Screw
K971297

(4) Osteomed Corp.
Auto-Drive Bone Screw
K974785

(5) Bioplate, Inc.
Bioplate® Rigid Fixation Bone Plating System for
Craniomaxillofacial Surgery
K972463/K022890

Description of the device

The Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery includes titanium alloy screws of varying diameters and lengths and are used for fixation of unalloyed, commercially pure titanium and titanium alloy plates to the craniofacial bony tissue.

Intended used of the device

The Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery is 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.

The supplementary label/labeling will be used for training and promotional purposes and does not affect the intended use of the devices.

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

The Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery has the same indications for use as the Bioplate, Inc., Walter Lorenz, Synthes USA, Osteomed Corp., and KLS-Martin predicate devices. All of the technical characteristics of the Bioplate Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery 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

APR 0 8 2003

Ms. Carol E. Jones
Chief Operating Officer
Bioplate, Incorporated
3643 Lenawee Avenue
Los Angeles, California 90016-4310

Re: K030806
Trade/Device Name: 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: March 12, 2003
Received: March 13, 2003

Dear Ms. Jones:

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. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim 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): K030806

Device Name: The Bioplate® Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery.

Indications for Use:

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Ken Melby Sr MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K030806