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FEB 0 8 2002

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

Summary of Safety and Effectiveness

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: Carol E. Jones

Trade Name of Device

The Bioplate® ZIP™ Craniotomy Fixation System

Common name

Plate, Cranioplasty, Preformed, Non-Alterable

Classification name

Plate, Cranioplasty, Preformed, Non-Alterable

Device Classification

84GXN (21CFR – 882.5330)

Predicate Devices

(1) Stryker Instruments
Leibinger Quik Disk
K993990

(2) Synthes (USA)
Synthes Cranial Flap Twist Clamp
K991860

(3) Synthes (USA)
Synthes Cranial Flap Tube Clamp
K992000

(4) Walter Lorenz Surgical
Rapidflap Cranial Clamp
K991029

(5) Ikonos Corp.
Sevrain Cranial Clamp
K971252

(6) Ikonos Corp.
Sevrain Cranial Clamp SCC-200 Series
K971408

(7) Aesculap, Inc.
Aesculap Craniofix Titanium Clamp System
K972332

(8) Bioplate, Inc.
The Bioplate® ZIP™ Craniotomy Fixation System
K013050

Description of the device

The Bioplate® ZIP™ Craniotomy Fixation System consists of two circular disks, in a parallel configuration, that are connected by an internal, serrated post. The devices will be available in several sizes with disk diameters in the range of 10mm to 18mm to be used for varying cranial closure techniques. The implant devices will be manufactured from 6Al4V titanium alloy material.

Intended used of the device

The Bioplate® ZIP™ Craniotomy Fixation System is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure. 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 Bioplate® ZIP™ Craniotomy Fixation System has the same indications for use as the predicate devices marketed by Bioplate, Inc., Synthes (USA), Stryker Instruments, Walter Lorenz Surgical, and Aesculap, Inc. All of the technical characteristics of The Bioplate® ZIP™ Craniotomy Fixation System 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

FEB 8 2002

Ms. Carol E. Jones
Bioplate, Inc.
6911 Melrose Avenue
Los Angeles, California 90038-3305

Re: K020088
Trade Name: Bioplate® ZIP™ Craniotomy Fixation System
Regulatory Number: 21 CFR 882.5330
Regulation Name: Performed Nonalterable Cranioplasty Plate
Regulatory Class: II
Product Code: GXN
Dated: January 8, 2002
Received: January 10, 2002

Dear Ms. Jones:

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 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 requirement, 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) 594-4659. 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" (21 CFR 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General Restorative
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPLICANT: Bioplate Inc.

510(k) NUMBER: (if known): K020088

DEVICE NAME: Bioplate® ZIP™ Craniotomy Fixation System

INDICATIONS FOR USE:

The Bioplate® ZIP™ Craniotomy Fixation System is intended to reattach a cranial bone flap to the surrounding cranium after a craniotomy procedure. The device is used to align and stabilized bony tissue while normal healing occurs. Each device is intended for single use only and may be combined only 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 X OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020088