JUL 21 2000

K001530

Summary of Safety and Effectiveness Information [510(k) Summary

May 15, 2000
Bioplate, Inc.
6911 Melrose Avenue
Los Angeles, CA 90038-3305
Tel: (323) 549-9500, Fax: (323) 935-0110
Contact: Eric V. Hohenstein

TRADE NAME The Bioplate Bioclip™ Craniotomy Fixation System

COMMON NAME Bone Plates

CLASSIFICATION NAME(S) Plate, cranioplasty, preformed, alterable

DEVICE CLASSIFICATION Class II, 21 CFR 872.4760 and 882.5320

PREDICATE DEVICE

The Bioplate Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery. (K980983)

Synthes Cranial Spring Clip (CSC), Synthes (USA) (K974206)

Ikonos Corporation SCC-100 (K971252).

DESCRIPTION

The Bioplate Bioclip™ Craniotomy Fixation System consists of a bone plate that utilizes a combination of fastening tabs and spring action to re-attach a cranial bone flap following a craniotomy procedure. Each device is provided unsterile and must be sterilized prior to use. The device is intended for single use only and may be combined only with other titanium and titanium alloy implants.

The Bioclip™ plates are manufactured of titanium 6Al – 4V ELI alloy, a material that has been implanted safely for many years. The material is recognized as acceptable for implantation purposes through device classification (for example, see 21 Code of Federal Regulations, sections 888.3030.)

INTENDED USE

The Bioplate Bioclip™ Craniotomy Fixation System is intended to re-attach a cranial bone flap following a craniotomy procedure.

The Bioclip™ Fixation System is contraindicated in the following conditions:

The saw gap in the cranial bone is greater than 2 mm in width.

The skull thickness is less than 4.5 mm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2000

Mr. Eric V. Hohenstein
Bioplate, Incorporated
6911 Melrose Avenue
Los Angeles, California 90038-3305

Re: K001530
Trade Name: The Bioplate Bioclip Craniotomy Fixation System
Regulatory Class: II
Product Code: JEY
Dated: May 15, 2000
Received: May 17, 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

APPLICANT: Bioplate, Inc.

510(k) NUMBER: (if known): K001530

DEVICE NAME: Bioplate Bioclip™ Craniotomy Fixation System

INDICATIONS FOR USE:

The Bioplate Bioclip™ Craniotomy Fixation System is intended to re-attach a cranial bone flap following a craniotomy procedure. The clip/plate is used to align and stabilize 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.

The Bioclip™ Fixation System is contraindicated in the following conditions:

The saw gap or fracture in the cranial bone is greater than 2 mm in width.

The skull thickness is less than 4.5 mm.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001530

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