K022033

JUL 19 2002

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

Sterile plate and screw kit configurations for use with the Bioplate® Titanium Fixation System

Common name

Bone plates and bone screws

Classification name

Bone Plate (21 CFR 872.4760)

Predicate Devices

(1) Walter Lorenz Surgical Instruments, Inc.
Lorenz 1.5mm Neuro Pack/Lorenz 2.0FT Plates (Sterile Version)
K972322

(2) Synthes (USA)
Maxillofacial Titanium Micro Set
K912932

(3) TiMesh Inc.
Softplates and screws
K923419, K923802, K973145

(4) Techmedica, Inc.
Anspach Fixation System
K921801

(5) Walter Lorenz Surgical Instruments, Inc.
Ultra-micro Titanium Cranial Osteosynthesis System
K910038

(6) KLS-Martin L.P.
KLS-Martin Micro Osteosynthesis System (1.0mm)
L944561

(7) KLS-Martin L.P.
KLS-Martin Micro Osteosynthesis System (1.5mm)
K944545

(8) KLS-Martin L.P.
KLS-Martin Oseosynthesis System (2.0mm)
K943347

(9) Sofamor Danek
Timesh System
K974017

(10) Howmedica, Inc.
Luhr Titanium Pan Fixation System
K945139

Description of the device

The sterile plate and screw kit configurations for use with the Bioplate® Titanium Fixation System includes a variety of plate configurations for different anatomical applications. Titanium alloy screws of varying lengths are included for fixation of the plates to the craniomaxillofacial bony tissue. Titanium alloy screws of varying lengths are included for fixation of the plates to the craniomaxillofacial bony tissue.

The bone plates will be manufactured of unalloyed, commercially pure titanium and titanium 6Al-4V ELI alloy. The materials adhere to the American Society of Testing and Materials (A.S.T.M) F67 Standards and The American Society for Testing and materials (A.S.T.M.) F136 Standard. The screws will be manufactured of a titanium 6Al-4V ELI alloy that meets The American Society for Testing and materials (A.S.T.M.) F136 Standard.

The plate and screw kit configurations are sterilized using gamma radiation sterilization methods. Successful completion of sterilization validation and packaging validation studies provides a high level of

assurance that sterility of the devices has been achieved and can be maintained.

Intended used of the device

The sterile plate and screw kit configurations for use with the Bioplate® Titanium Fixation System are intended for use in non-load bearing fixation, including, but not limited to cranial bone fixation and brow fixation, and the treatment of fractures and reconstructive procedures of the craniomaxillofacial skeleton. 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 sterile plate and screw kit configurations for use with the Bioplate® Titanium Fixation System have the same indications for use as the Bioplate, Inc., Wurzburg, Synthes, TiMesh, and KLS-Martin predicate devices. All of the technical characteristics of the sterile plate and screw kit configurations for use with the Bioplate® Titanium 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

JUL 19 2002

Bioplate, Incorporated
C/O Mr. Bruce F. Mackler
Heller, Ehrman, White & Mcauliffe
815 Connecticut Avenue NW
Washington, D. C. 20006-4004

Re: K022033
Trade/Device Name: Sterile Plate & Screw Kit Configurations for use with the Bioplate® Titanium Fixation System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: June 10, 2002
Received: June 21, 2002

Dear Mr. Mackler:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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): K022033

Device Name: Sterile plate and screw kit configurations for use with the Bioplate® Titanium Fixation System

Indications for Use:

The sterile plate and screw kit configurations for use with the Bioplate® Titanium Fixation System are intended for use in non-load bearing fixation, including cranial bone fixation and brow fixation, and the treatment of fractures and reconstructive procedures of the craniomaxillofacial skeleton and. 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 ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K022033