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SEP 25 1997

BIOMEDICS, INC.
536 South Rimpau Boulevard
Los Angeles, California 90020-4832
Tel: (213) 934-4700, FAX: (213) 934-8212

Summary of Safety and Effectiveness

This statement regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Bioplate Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery is manufactured of commercially pure titanium and a titanium 6A1-4V ELI alloy, materials that have been implanted safely for many years. These materials are recognized as acceptable for implantation purposes through device classification (for example, see 21 Code of Federal Regulations, sections 888.3030.)

The plates are substantially equivalent in construction and design to the predicate devices manufactured by Biomedics, Inc., W.L. Lorenz and Synthes (USA.) The screws are manufactured of a titanium alloy that is at least equivalent to commercially pure titanium in strength and they are substantially equivalent in design to the predicate devices.



SEP 25 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Carol E. Jones
Biomedics, Incorporated
536 South Rimpau Boulevard
Los Angeles, California 90020

Re: K972463
Trade Name: The Bioplate Rigid Fixation Bone Plating
System for Craniomaxillofacial Surgery
Regulatory Class: II
Product Code: JEY
Dated: July 1, 1997
Received: July 1, 1997

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.

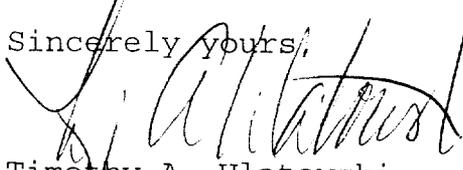
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4618. 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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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

510(k) Number (if known): _____

The plate and screw designs for use in conjunction with the Bioplate Rigid Fixation Bone Plating
Device Name: System for Craniomaxillofacial Surgery

Indications For Use:

The plate and screw designs for use in conjunction 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 facial skeleton and non-load bearing fixation, including cranial bone fixation, brow fixation, zygomatic fixation, orbital rim fixation, maxillary fixation, graft fixation and membrane 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)

Susan Punnes

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972463

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)