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

NOV 1 9 2002

Summary of Safety and Effectiveness - K022986

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® Battery Powered Drill

Common name

Battery powered drill

Classification name

Electric cranial drill motor

Device Classification

84HBC (21CFR – 882.4360)

Predicate Devices

(1) Sodem Systems
Sodem Systems
K012457

(2) Sodem Systems
Sodem Systems
K012453

(3) Anspach

Anspach eMax Drill System
K011444

(4) Aesculap, Inc.
Microspeed EC Motorsystem
K003612

(5) Linvatec Corporation
Advantage™ Drive System
K002523

(6) Medicon, E.G.
Servotronic EC100 System
K972857

Description of the device

The Bioplate® Battery Powered Drill is comprised of a metal housing, containing the motor, designed to withstand steam sterilization. Two forward speeds are activated using control buttons on the body of the unit. There is no reverse. The operating portion of the instrument has a quick release mechanism that is designed to hold stainless steel drill bits for drilling pilot holes into bony tissue prior to insertion of self-tapping bone screws. Four (4) AAA batteries (sterile, unitized or non-sterile) are inserted into the back portion of the handle prior to use.

Intended used of the device

The Bioplate® Battery Powered Drill **is intended to be used to drill pilot holes to facilitate the insertion of self-tapping bone screws in surgical procedures on a patient's skull.**

The Bioplate® Battery Powered Drill is not intended for bone cutting or bone shaping indications.

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

The Bioplate® Battery Powered Drill has similar indications for use as the predicate devices marketed by Sodem Systems, Linvatec Corporation, Aesculap, Inc., Anspach Inc. and Medicon, E. G. The technical characteristics of The Bioplate® Battery Powered Drill are substantially equivalent to the corresponding characteristics of the predicate devices for the same application, and any minor differences raise no new issues of safety and efficacy.

Revised 11/1/02
Carol E. Jones
Bioplate, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2002

Bioplate Inc.
Bruce F. Mackler
c/o Heller, Ehrman, White & McAuliffe
815 Connecticut Avenue, NW
Washington, D.C. 20006-4004

Re: K022986
Trade/Device Name: Bioplate® Battery Powered Drill
Regulation Number: 882.4360
Regulation Name: Electric cranial drill motor
Regulatory Class: Class II
Product Code: HBC
Dated: September 9, 2002
Received: September 9, 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), 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" (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,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
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): K022986

DEVICE NAME: Bioplate® Battery Powered Drill

INDICATIONS FOR USE:

The Bioplate® Battery Powered Drill is intended to be used to drill pilot holes to facilitate the insertion of self-tapping bone screws in surgical procedures on a patient's skull.

The Bioplate® Battery Powered Drill is not intended for bone cutting or bone shaping indications.

(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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022986