



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2000

Mr. Michael Parmenter
Fischer Imaging Corporation
12300 North Grant Street
Denver, CO 80241-3120

Re: K991293
Epstim Software and Bloom DTU Electrophysiology Program
Stimulator
Regulatory Class: II (two)
Product Code: JOQ
Dated: March 27, 2000
Received: March 28, 2000

Dear Mr. Parmenter:

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 control provisions of the Act. The general control 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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

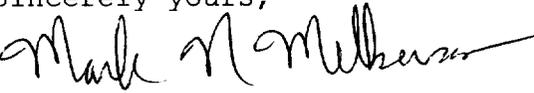
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for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4648. 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/dsma/dsmamain.html>".

Sincerely yours,



for

James E. Dillard III
Director
Division of Cardiovascular
And Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K991293

DEVICE NAME: EPStim and DTU-215

INDICATIONS FOR USE:

The DTU-215 Programmable Electrophysiology Stimulator with the EPStim Electrophysiology Stimulator Control Program is indicated for patients that are candidates for electrophysiology studies for the diagnosis, and the planning of treatment for super-ventricular, ventricular tachyarrhythmias, conduction disorders, syncope and other miscellaneous arrhythmias.

The EPstim is intended for assisting a physician in performing an electrophysiology study by providing automated control of the DTU-215 Programmable Stimulator. The system provides for compilation, storage and rapid execution of a customized series of stimulator commands (stimulation protocols), and automatic determination of capture during cardiac electrophysiological testing.

The DTU-215 Programmable Stimulator is intended for use in the electrophysiology laboratory during electrophysiology testing under the direction of qualified personnel trained to administer electrophysiological procedures.

(Division of) _____
Division of _____ Laboratory,
and
510(k) Number _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-9)

for Mark A. Miller K991293
(Division Sign-Off)
Director, Cardiovascular, Respiratory,
and _____ Devices
510(k) Number _____