



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 14 2004

EP MedSystems  
c/o Mr. James Kuhn, Jr.  
Director of Regulatory Affairs  
Cooper Run Executive Park  
575 Route 73 North – Bldg. D  
West Berlin, NJ 08091-9293

Re: K041442

Trade Name: EP-4 Clinical Stimulator  
Regulation Number: 21 CFR 870.1750  
Regulation Name: External Programmable Pacemaker Pulse Generator  
Regulatory Class: Class II (two)  
Product Code: JOQ  
Dated: August 30, 2004  
Received: August 31, 2004

Dear Mr. Kuhn:

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) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.

Division Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



Cooper Run Executive Park  
575 Route 73 North, Building D  
West Berlin, NJ 08091-9293  
Tel: (856) 753-8533  
Fax: (856) 753-8544



May 24<sup>th</sup>, 2004

## Indications for Use

510(k) Number (if known): K041442

Device Name: EP-4 Clinical Stimulator

### Indications For Use:

The EP-4 Clinical Stimulator is intended to be used for diagnostic electrical Stimulation of the heart for the purpose of refractory measurements, initiation and termination of tachyarrhythmias, and measurements of electrical conductions.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bhummer  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K041442

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