

6. 510(k) SUMMARY

OCT 26 2007

General Information

Classification	Class II
Trade Name	StimLab™ Dual Control Computerized Diagnostic Programmable Cardiac Stimulator
Manufacturer	Micropace Pty Ltd Suite 7, 186-188 Canterbury Rd, Canterbury NSW 2193 Sydney Australia
Contact	Dr Michael Cejnar Managing Director

Intended Use / Indications for use (unaltered from predicate device):

The StimLab cardiac stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction. This is the same intended use as previously cleared for the EPS320, K011826.

Predicate Device

The predicate devices is the Micropace EPS320 Cardiac Stimulator – K011826, 24 Jan 2002

Device Description

The StimLab™ is an EPS320 cardiac stimulator modified by the addition of a remote bedside touch monitor. The system consists of a manually controllable pulse generator issuing standard cardiac pacing pulses, normally controlled by a separate computer containing a graphic touch user interface and pre-programmed complex stimulation patterns suited to electrophysiology (EP) studies. In the StimLab™, a second remotely locatable beside control touch screen duplicates the video display and touch controls allowing verification and control of stimulator settings from two locations, one typically located in an electrophysiology laboratory central control room and the second at the operating table. The device is not a life support device and makes no diagnoses.

Materials

The materials in the StimLab™ Cardiac stimulator are suitable for their intended use and have been used in previously cleared products. The device is not patient contacting and therefore no biocompatibility testing was required.

Testing

Appropriate risk-analysis driven product testing was conducted to evaluate conformance to product specification and substantial equivalence to the predicate device.

Summary of Substantial Equivalence

The StimLab™ Cardiac Stimulator is equivalent to the predicate product. The indications for use, basic overall function, and materials used are equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2007

Micropace PTY LTD
c/o Dr. Michael Cejnar
Founding Managing Director
Canterbury, NSW
Australia 2193

Re: K072200
StimLab™ Programmable Cardiac Electrophysiological Stimulator
Regulation Number: 21 CFR 870.1750
Regulation Name: External programmable pacemaker pulse generator
Regulatory Class: Class II (two)
Product Code: JOQ
Dated: October 17, 2007
Received: October 19, 2007

Dear Dr. Cejnar:

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.

Page 2 – Dr. Michael Cejnar

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. Indications for Use Statement

510(k) Number (if known): K072200

Device Name:

StimLab™ Programmable Cardiac Electrophysiological Stimulator

Indications For Use:

The StimLab Cardiac stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction.

B. Zimmerman
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072200