

**SUMMARY OF SAFETY AND EFFECTIVENESS**

The Irvine Biomedical, Inc. Luma-Cath™ Steerable Electrophysiology Catheter System is a multiple-electrode electrophysiology recording catheter and its connecting cable. The diameter of the catheter is between 6 and 8 French. The diameter of the electrodes is between 6 and 8 French. There is a lumen with nominal internal diameter of 0.036 inch.

The electrophysiology catheters are commonly placed at the high right atrium, right ventricular apex, and His bundle. The Luma-Cath™ Steerable Electrophysiology Catheters are used for electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies.

The components of the Luma-Cath™ Steerable Electrophysiology Catheter System are all biocompatible and have all been tested for use in the body. Specifically, the patient contact materials are the same as the predicate devices and have been approved by the FDA. The sterilized, finished Luma-Cath™ Steerable Electrophysiology Catheter has passed the performance tests. Its manufacturing process will follow the Good Manufacturing Practice with quality assurance and validated sterilization process. Therefore, we believe the Luma-Cath™ Steerable Electrophysiology Catheter on this submission to be safe and effective.

The accessory cables used to connect the Luma-Cath™ Steerable Electrophysiology Catheters to a recorder are conventional and are cleared in the 510(k) K961924, which comply with Section 12A of the Underwriters Laboratories UL 544 Standard for Safety.



DEC 10 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Roger Tu  
Vice President - QA/RA  
Irvine Biomedical, Inc.  
2146-A Michelson Drive  
Irvine, CA 92612

Re: K991878  
Luma-Cath™ Steerable EP Catheters  
Regulatory Class: II (two)  
Product Code: DRF  
Dated: September 10, 1999  
Received: September 14, 1999

Dear Mr. Tu:

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 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.

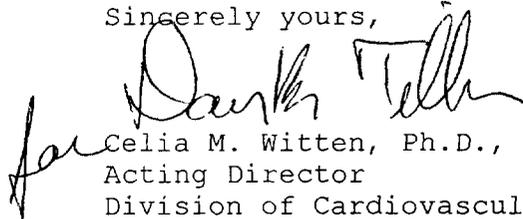
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice 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 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.

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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" (21CFR 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

Celia M. Witten, Ph.D., M.D.  
Acting Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**510(k) Number (if known):**

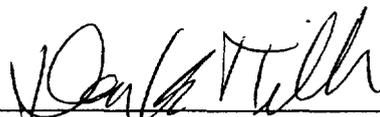
**Device Name:** IBI Luma-Cath™ Steerable EP Catheters

**Indications For Use:** The IBI Luma-Cath™ Steerable Electrophysiology Catheters are used for electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies. The catheters are commonly placed in the high right atrium, right ventricular apex, and the His bundle.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off)  
Division of Cardiovascular, Respiratory, and  
Neurological Devices  
510(k) Number K991878

Prescription Use  Or Over-The-Counter Use   
(Per 21 CFR 801.109)