

JUL 25 1998

K982232

**SUMMARY OF SAFETY AND EFFECTIVENESS
(K982232)**

The Irvine Biomedical, Inc. IBI-1100™ Bi-directional Steerable Electrophysiology Catheter System is a multiple-electrode electrophysiology recording catheter and its connecting cable. The diameter of the catheter is between 5 and 8 French. The diameter of the tip electrode is between 5 and 8 French.

The electrophysiology catheters are commonly placed at the high right atrium, right ventricular apex, and HIS bundle. The IBI-1100™ Bi-directional Steerable Electrophysiology Catheters are used for electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies.

The components of the IBI-1100™ Bi-directional 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 IBI-1100™ Bi-directional Steerable Electrophysiology Catheter has passed the biocompatibility and performance tests. Its manufacturing process will follow the Good Manufacturing Practice with quality assurance and validated sterilization process. Therefore, we believe the IBI-1100™ Bi-directional Steerable Electrophysiology Catheter on this submission to be safe and effective.

The accessory cables used to connect the IBI-1100™ Bi-directional Steerable Electrophysiology Catheters to a recorder are conventional and comply with Section 12A of the Underwriters Laboratories UL 544 Standard for Safety.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 1998

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

Re: K982232
IBI-1100™ Bi-directional Steerable Electrophysiology
Catheter System
Regulatory Class: II (two)
Product Code: DRF
Dated: June 23, 1998
Received: June 25, 1998

Dear Dr. 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 (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 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.

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/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K982232

DEVICE NAME: IBI-1100™ Bi-directional Steerable Electrophysiology Catheter System

INDICATIONS FOR USE:

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.

[Handwritten Signature]

(Division Sign-Off)
Division of Cardiovascular, Respiratory
and Neurological Devices

510(k) Number K982232

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)