

SECTION 14

510(k) Summary of Safety and Effectiveness

MAR 20 2007

Sponsor: Irvine Biomedical Inc,
2375 Morse Avenue
Irvine, CA 92614, USA

Contact Person: Rohit Patel
Sr. Regulatory Affairs Specialist
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Submission date: December 29, 2006

Device Name: IBI *Inquiry*™ ClearICE™ Intracardiac Echocardiography Catheter

Common Name: Intracardiac/Intravascular Ultrasound Catheter

Classification:

Regulatory Class: II

Regulatory Category: Tier II

	FR Number	Product Code
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Diagnostic Ultrasound Catheter	870.1200	74-DQO

Predicate Devices:

- #K042593 (January 5, 2005) cleared as ACUSON AcuNav 8Fr Ultrasound Catheter.
- #K033650 (February 24, 2004) cleared as ACUSON AcuNav 90/10 Diagnostic Ultrasound Catheter.
- #K992632 (November 8, 2001) cleared as ACUSON AcuNav Diagnostic Ultrasound Catheter.

Device Description:

The IBI *Inquiry*™ ClearICE™ Intracardiac Echocardiography Catheter is comprised of a single-use, disposable ultrasonic phased-array imaging transducer. A *Inquiry* ClearICE catheter is steerable catheter, 9 Fr (2.97 mm) in diameter, 90 cm to 110 cm insertable length and available in various curve configuration.

The distal portion of the catheter can be deflected in four directions in two orthogonal planes: left-right (in a plane perpendicular to imaging plane) and anterior-posterior (in a plane coincident with the image plane). Bi-directional steering controlled by push/pull

handle mechanism and quad-directional steering controlled by a push/pull mechanism and rotating knob.

The non-sterile, reusable GE Connector Cable is used to connect IBI Inquiry™ ClearICE™ Intracardiac Echocardiography Catheter to the GE Vivid *i* Ultrasound system. The IBI Inquiry™ ClearICE™ Intracardiac Echocardiography Catheter is used with commercially available GE Connector Cable and Vivid- *i* Diagnostic Ultrasound System.

The IBI Inquiry™ ClearICE™ Intracardiac Echocardiography Catheter is comprised of three major components: (1) the catheter itself; (2) the steering mechanism; and (3) the reusable GE Connector Cable & GE Vivid *i* Ultrasound System.

The IBI Inquiry™ ClearICE™ Intracardiac Echocardiography Catheter is substantially equivalent to ACUSON AvuNav ultrasound catheters that are already cleared for USA distribution under the following 510(k) PreMarket Notification numbers:

- #K042593 (January 5, 2005) cleared as ACUSON AcuNav 8Fr Ultrasound Catheter.
- #K033650 (February 24, 2004) cleared as ACUSON AcuNav 90/10 Diagnostic Ultrasound Catheter.
- #K992632 (November 8, 2001) cleared as ACUSON AcuNav Diagnostic Ultrasound Catheter.

The IBI Inquiry™ ClearICE Intracardiac Echocardiography Catheter designed and validated in compliance with the following standards:

- ISO 13485:2003: Medical devices -- Quality management systems -- Requirements for regulatory purposes
- 21 CFR Section 820: FDA Quality System Regulation
- Guidance Document-- 9/30/1997: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers
- ISO 14971:2001: Medical devices – Application of risk management to medical devices
- ISO 10555-1:1997: Sterile, single-use Intravascular catheter - Part 1: General requirements
- IEC/EN 60601-1-1:2001: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-2:1998: Medical Electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
- BS EN 60601-1:1990, BS 5724: Part1: 1989: Medical electrical equipment - Part 1: General requirements for safety
- ISTA 2A: Performance Test for Individual Packaged Products 150 lb or Less
- ANSI / AAMI / ISO 11135:1994: Medical devices – validation and routine control of Ethylene Oxide Sterilization
- BS EN550:1994: Sterilization of Medical Devices - Validation and Routine Control of Ethylene Oxide sterilization

- BS EN556:2001: Sterilization of Medical Devices - Requirements for Terminally Sterilized Device to be labeled "Sterile"
- AAMI TIR28:2001: Product adoption and process equivalency for ethylene oxide sterilization
- ISO 10993-7:1996: Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
- ISO 10993-1:2003: Biological evaluation of medical devices - Part 1: Evaluation and testing

Indication for Use:

The IBI Inquiry™ ClearICE™ Intracardiac Echocardiography Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac anatomy and physiology as well as visualization of other devices in the heart.

Technological Comparison to Predicate Device:

The IBI's Inquiry™ Intracardiac Echocardiography Catheter is substantially equivalent in its technologies and functionality to the ACUSON AcuNav ultrasound catheters that are already cleared for USA distribution under the following 510(k) PreMarket Notification numbers #K042593 (January 5, 2005), #K033650 (February 24, 2004), and #K992632 (November 8, 2001).

The IBI's Inquiry™ Intracardiac Echocardiography Catheter and ACUSON AcuNav ultrasound catheters are ultrasound-tipped catheter devices for ultrasound imaging.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Rohit Patel
Sr. Regulatory Affairs Specialist
Irvine Biomedical, Inc.
2375 Morse Avenue
IRVINE CA 92614

MAR 20 2007

Re: K070011

Trade Name: IBI *Inquiry*[™] ClearICE[™] Intracardiac Echocardiography Catheter
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: ITX
Regulation Number: 21 CFR §870.1200
Regulation Name: Diagnostic intravascular catheter
Produce Code: DQO
Regulatory Class: II
Dated: December 29, 2006
Received: January 3, 2007

Dear Mr. Patel:

We have reviewed your Section 510(k) premarket 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.

This determination of substantial equivalence applies to the following transducers intended for use with the IBI *Inquiry*[™] ClearICE[™] Intracardiac Echocardiography Catheter, as described in your premarket notification:

Transducer Model Number - *Inquiry*[™] ClearICE[™]

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.

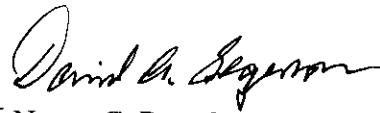
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 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>

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (240) 276-1373.

Sincerely yours,



for Nancy C. Brogdon

Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

SECTION 13

Indications for Use

510(k) Number (if known): K070011

Device Name: IBI Inquiry™ ClearICE™ Intracardiac Echocardiography Catheter

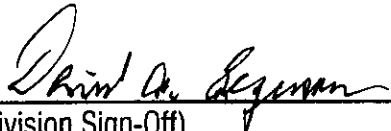
Indications for Use:

The IBI Inquiry™ ClearICE™ Intracardiac Echocardiography Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac anatomy and physiology as well as visualization of other devices in the heart.

Prescription Use (Part 21 CFR 801 Subpart D) ~~AND/OR~~ Over-The-Counter Use (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K070011

Page 1 of 1

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K070011

Device Name: Inquiry™ ClearICE™ Intracardiac Echocardiography Catheter

Indications for Use: The Inquiry™ ClearICE™ Intracardiac Echocardiography Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac anatomy and physiology as well as visualization of other devices in the heart.

Transducer: Inquiry™ ClearICE™ Intracardiac Echocardiography Catheter

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation											
	A	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic												
Fetal / Obstetrics												
Abdominal ^[1]												
Pediatric												
Small Organ (specify) ^[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac ^[3]		N	N	N	N	N	N	N	N	N		
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intra-luminal		N	N	N	N	N	N	N	N	N		
Peripheral Vascular												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Other (intra-cardiac)		N	N	N	N	N	N	N	N	N		

N = new indication; P = previously cleared by FDA; E = added under Appendix E

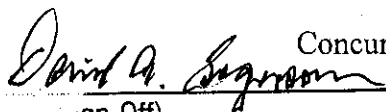
Notes: [*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

Prescription Use X
(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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



(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Reproductive, Abdominal, and
Radiological Devices

510(k) Number K070011