K080223
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510(k) SUMMARY

ImaCor Zura TEE System

JUN 24 2008

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

ImaCor LLC
50 Charles Lindbergh Blvd
Suite 200
Uniondale, NY 11553

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Contact Person: Richard C. Lanzillotto

Date Prepared: January 16, 2008

Name of Device and Name/Address of Sponsor

ImaCor Zura TEE System

ImaCor LLC 50
Charles Lindbergh Blvd
Suite 200
Uniondale, NY 11553

Common or Usual Name

Transesophageal Echo Imaging System

Classification Name

Ultrasonic Pulsed Echo Imaging System (892.1560) with a Diagnostic Ultrasonic Transducer (892.1570) or Echocardiograph (870.2330)

Product Codes

IYO, ITX, DXK

Device Class

II

Predicate Devices

Ultrasonix Modulo (K042326)
Sonosite Ultrasound Diagnostic System (K043559)
GE Vivid 7 (K051449)

Intended Use / Indications for Use

The ImaCor Zura TEE System is intended for use in the episodic assessment of cardiac function using transesophageal echocardiography. It is indicated for use in clinical settings, including long-term settings such as the ICU, for an indwelling time period not to exceed 72 hours. The ImaCor Zura TEE System is not intended for pediatric use.

Technological Characteristics

The ImaCor TEE System consists of three main components:

1. Ultrasound Machine:

A TEE predicate device optimized for use with ImaCor miniaturized probe.

2. Ultrasound Probe (The "Blue Probe"):

A miniaturized TEE probe optimized for longer dwell time relative to standard TEE probes enables use in longer term clinical settings such as the ICU. The probe distal tip is flexed upward transiently to obtain standard TEE images.

3. Ultrasound Imaging Software:

The software controls standard ultrasound machine functions such as imaging, recording and measuring. Continuous imaging is limited by a 20 minute software interlock should the operator mistakenly leave the machine in continuous imaging mode, thus limiting the potential unintentional exposure of the patient's mucosal tissue to acoustic energy. Maximum probe face temperature is limited according to FDA consensus standard IEC 60601-2-37.

Performance Data

Performance data demonstrate that the miniaturization of the ImaCor probe and ultrasound transducer, relative to standard size predicate TEE probes does not impact safety or effectiveness. Phantom measurement data shows that the ImaCor Zura TEE device is equivalent to predicate TEE devices with respect to effectiveness.

The ImaCor Zura TEE system was also subject to preclinical (animal) studies and confirmatory clinical studies.

Substantial Equivalence

The ImaCor Zura TEE System is as safe and effective as the predicate devices. The ImaCor Zura has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the ImaCor Zura and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the ImaCor Zura is as safe and effective as the predicates. Thus, the ImaCor Zura is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2008

ImaCor, LLC
% Steven B. Datlof, M.D., J.D.
Official Correspondent
Hogan & Hartson LLP
1835 Market Street, 28th Floor
PHILADELPHIA PA 19103

Re: K080223
Trade/Device Name: ImaCor Zura TEE System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX, and DXK
Dated: May 28, 2008
Received: May 28, 2008

Dear Dr. Datlof:

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 ImaCor Zura TEE System, as described in your premarket notification:

Transducer Model Number

Zura TEE

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 Lauren Hefner at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Statement

510(k) Number (if known): K080223

Device Name: ImaCor Zura TEE System

Indications for Use:

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Prescription Use __√__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080223