K113832

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MAR - 6 2012

510(k) Summary of Safety and Effectiveness
As required by 21 CFR, part 807.92

Submitted By:	Blacktoe Medical III, Inc. 8305 SW Creekside Place, Suite C Beaverton, OR. 97008 Phone 503-636-6999 Fax 503-715-0597
Contact:	Kendra Rathkey Manager, Quality and Regulatory
Date Prepared:	December 22, 2011
Proprietary Name:	SonicEye® Ultrasound Transducer
Common / Usual Name:	Diagnostic Ultrasound Transducer
Product Classification:	892.1570, ITX, class II, Diagnostic Ultrasound Transducer
Device Description:	The SonicEye® is a finger-mounted ultrasound transducer designed to attach to the SonoSite MicroMaxx® ultrasound system, in place of the SonoSite SLA/13-6 transducer, to acquire ultrasound images for display on the system. The SonicEye® transducer connects to the MicroMaxx® system's standard transducer port. Upon connection, the visual display on the MicroMaxx® system denotes that a type "SLA" transducer is in operation. The SonicEye® acoustic array is located in a small ring structure worn on the user's finger. The array is a linear type, with a 5-12 MHz frequency range, average scan depth of 3 cm and maximum scan depth of 6 cm. The array contains 128 elements spaced at 200 micron pitch, forming an azimuthal total aperture size of 25.6 mm. The elevational aperture height is 4 mm. The array supports acquisition of ultrasound images in 2D, M-Mode, Pulsed Wave (PW) Doppler, and Color Power Doppler, or in a combination of these modes.
Intended Use:	The SonicEye® ultrasound transducer is a general-purpose transducer intended for use by a qualified clinician for diagnostic

ultrasound imaging or fluid flow analysis of the human body in the following applications: Pediatric, Small Organ (breast, thyroid, testicles, prostate), Musculo-skeletal (conventional and superficial), and Peripheral Vessel.

Technological Characteristics: The SonicEye® was designed to make a conventional hand held probe wearable on the finger. This ergonomic form factor, enables imaging while freeing the operator to use the hand to assist in other elements of the examination.

Elements of the probe related to image generation and safety, for example array design, housing, cabling and insulation are similar to conventional probes and differ only in form factor. Safety testing of the SonicEye® and comparison testing with the predicate probe show no differences in safety or image quality that would impact the effectiveness of the device.

Substantial Equivalence: The SonicEye® transducer is substantially equivalent to the cleared Sonosite SLA/13-6 Transducer for MicroMaxx® high-resolution ultrasound system (K053069) with regard to safety and effectiveness.

Summary of Benefits: Wearing the transducer on the finger potentially provides several benefits over a hand-held probe including:

- The finger form factor allows the clinician to simultaneously palpate or elicit symptoms through touch with the finger and hand using the probe, thus correlating symptoms with diagnostic image generation.
- The probe leverages innate hand/finger/eye coordination and innate spatial orientation of the finger probe to improve imaging dexterity. It is especially suitable for performing needle-guided ultrasound procedures.
- The probe can be used with conventional gloves or commercially available transducer sheaths, facilitating clinical workflow for ultrasound-guided procedures.
- The hand performing the exam can be used to stabilize the region being scanned.

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Test Summary & Conclusion: The SonicEye transducer has been designed to conform with the following product safety standards:

Reference Number	Title
IEC 60601-1:1990 plus A1:1993 and A2:1995	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2008	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-2-37:2007	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
NEMA UD-2:2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA UD-3:2004	Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
ISO 10993:2009	Biological evaluation of medical devices - Part 1: Evaluation and Testing

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ms. Kendra Rathkey
Manager, Quality & Regulatory
Blacktoe Medical III, Inc.
8305 Creekside Place, Suite C
BEAVERTON OR 97008

MAR = 6 2012

Re: K113832
Trade/Device Name: SonicEye Transducer for use with SonoSite MicroMaxx® Ultrasound System
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagonstic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: December 22, 2011
Received: December 27, 2011

Dear Ms. Rathkey:

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 SonoSite MicroMaxx® Ultrasound System, as described in your premarket notification:

Transducer Model Number

SonicEye Transducer for use with SonoSite MicroMaxx® Ultrasound System

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 895. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Mary S Pastel for

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Diagnostic Ultrasound Indications for Use

510(k) Number (if known): _____

Device Name: SonicEye Transducer for use with SonoSite MicroMaxx® Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro)							
Laparoscopic							
Pediatric	N	N	N		N	B+M, B+CD, B+PWD	
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M, B+CD, B+PWD	
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skeletal (Conventional)	N	N	N		N	B+M, B+CD, B+PWD	
Musculo-skeletal (Superficial)	N	N	N		N	B+M, B+CD, B+PWD	
Intravascular							
Other (Specify)							
Cardiac Adult							
Cardiac Pediatric							
Intravascular (Cardiac)							
Trans-esoph. (Cardiac)							
Intra-cardiac							
Other (Specify)							
Peripheral vessel	N	N	N		N	B+M, B+CD, B+PWD	
Other (Specify)							

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

Additional Comments:

Prescription Use (per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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