K043139

510(k) Summary – USCOM 1A

510(k) Summary

Per 21 CFR Part 807.92

FEB 15 2005

Section a):

Date Prepared	Tuesday, 9th Nov 2004
Official Contact	Mr Nick Schicht USCOM Ltd Level 7 10 Loftus Street Sydney, Australia 2000
Classification Reference	90 IYN
Product Code	21 CFR 892.1550
Common/Usual Name	Pulsed-Doppler
Proprietary Name	USCOM 1A
Predicate Device(s)	1): (K020789) GE Vivid 3 Expert/Pro Diagnostic Ultrasound System. Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN 2): (K011439) BioZ.com HemoDynamic Monitor, 21 CFR 870.2770, DSB
Reason for submission	New Device
Indications for Use	USCOM 1A records and monitors beat-to-beat cardiac heamodynamics in paediatric and adult patients. Its recording and storage of patient information provides trending information of cardiovascular performance for quantitative evaluation. The USCOM 1A is for use by clinicians in the hospital environment.

Device Description

The USCOM 1A is a non-invasive tool that measures and records changes in the heamodynamic status of a patient.

It is a portable Continuous Wave Doppler device using an Ultrasonic Transducer to measure blood flow. The USCOM 1A consists of an easy to use touch screen display with monitoring, trending and storage functionality. Using the touch screen the user navigates intuitive and simple screens to enter patient details and perform examinations.

Targeting the patient's pulmonary or aortic valves transcutaneously, the blood flow profile can be displayed and measured. From the measured blood flow profile, the clinician can determine a number of parameters including Stroke Volume and Cardiac Output.

The USCOM 1A saves the measures in a patient file. Multiple saved measures over time are displayed in a trend graph allowing the clinician to view the patient's change in heamodynamic status. Reports can be generated on patient measures which can be printed and exported for analysis.

The device is portable, weighing less than 7 kilograms and incorporates an internal battery.

Comparison with Predicate Device(s)

The USCOM 1A system is of comparable type and is substantially equivalent to the:

- GE Vivid 3 Expert/Pro system for CW Doppler performance having similar technological characteristics for safety and effectiveness features, design, construction and materials with the similar Intended Use and clinical application, and;
- BioZ.com HemoDynamic Monitor for patient data storage, and retrieval functionality.

Section b):

Non-clinical tests

The device has been tested for acoustic output, electrical safety including thermal properties, EMC, biocompatibility, mechanical and environmental characteristics and has been found to comply with applicable medical device safety and performance standards.

Clinical tests

None required. Testing to consensus performances standards and well proven test methods is sufficient to demonstrate that the Continuous Wave Doppler technology used in the USCOM 1A, can perform clinical requirements as intended by USCOM Ltd.

Conclusion

The intended use and key features are consistent with traditional clinical practice, FDA guidelines and established methods of patient examination. The product development and design of the device conforms to 21 CFR 820 Quality System Regulation (QSR) and ISO 13485 Quality Management System standards for medical device manufacturers. The product is designed to conform to FDA consensus standards such as electrical safety, EMC and performance, compliance has been verified through use of independent test houses. Therefore, it is concluded that the USCOM 1A system is substantially equivalent with respect to safety and effectiveness to the predicate devices, Vivid 3 from GE Medical Systems (K020789) and BioZ from CardioDynamics (K011439)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2005

USCOM Ltd.
% Ms. Christina L. Kichula
Manager, Regulatory Affairs
PPD Medical Device
1700 Rockville Pike, Suite 400
ROCKVILLE MD 20852

Re: K043139
Trade Name: USCOM 1A
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance plethysmograph
Product Code: 74 DSB
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN and ITX
Dated: January 27, 2005
Received: January 27, 2005

Dear Ms. Kichula:

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 USCOM 1A, as described in your premarket notification:

Transducer Model Number

2.2MHz 10mm diameter probe
2.2MHz 15mm diameter probe

3.3MHz 10mm diameter probe

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

If you have any questions regarding the content of this letter, please contact REVIEWER at (301) 594-1212.

Sincerely yours,

David A. Lyon

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

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

USCOM 1A

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric					N					
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments:

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043139

Diagnostic Ultrasound Indications for Use Form

USCOM 1A *with* 2.2MHz 10mm diameter probe

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric					N					
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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David A. Lyon
(Division Sign-Off)
Division of Reproductive, **Abdominal,**
and Radiological Devices
510(k) Number K043139

Diagnostic Ultrasound Indications for Use Form

USCOM 1A *with* 2.2MHz 15mm diameter probe

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric					N					
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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(Division Sign-Off)
Division of Reproductive, Abdominal,
[illegible] Devices
[illegible] Number K043139

Diagnostic Ultrasound Indications for Use Form

USCOM 1A *with* 3.3MHz 10mm diameter probe

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric					N					
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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