K091518

510(k) Summary

JUN 18 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Feb. 10, 2009

1. Company and Correspondent making the submission:

Name – Mcube Technology Co., Ltd.

Address – #803, Shinnae-technotown, 485 Sangbong-Dong
Chungnang-Ku, Seoul, Korea 131-220

Telephone – +82-2-3421-7780

Fax – +82-2-3421-7076

Contact – Mr. Seung-Sub Shin

Internet – http://www.mcubetech.co.kr

2. Device :

Trade/proprietary name	: CUBEscan / BioCon-500
Common Name	: Diagnostic Ultrasound System with Accessories
Classification Name	: system, imaging, pulsed echo, ultrasonic

3. Predicate Device :

Manufacturer	: VERATHON INCORPORATED
Device	: BVI 9400
510(k) Number	: K071217(Decision Date - May 17. 2007)
Manufacturer	: Mediwatch Ltd.
Device	: Multiscan
510(k) Number	: K053325 (Decision Date – Dec. 7. 2005)

4. Classifications Names & Citations :

21CFR 892.1560, 1570, IYO, ITX, system, imaging, pulsed echo, ultrasonic, Class2

5. Description :

The **BioCon-500™** is a portable ultrasound system for measuring the urine volume in a patient. **BioCon-500™** transmits ultrasound signals to the abdomen of a patient and receives the echoed signals. Using the echoed signals the system detects the bladder outlines and calculates the volume in bladder outlines.

BioCon-500™ has a Pre-Scan function, which shows the ultrasound images for a horizontal plane consisted of the echoed signals. The Pre-Scan function helps a user locate the bladder easily and get more accurate results.

A user can print the results using a built-in thermal printer after measurements right away.

Also using the optional CubeScanPC software you can upload the saved data in a device's flash ROM to a computer for reviewing the scan results.

6. Indication for use :

The BioCon-500™ is a B-mode pulsed-echo ultrasound device. The BioCon-500™ is intended as a portable battery-operated device. The BioCon-500™ is intended to project ultrasound energy through the abdomen of the patient to obtain images of the bladder and to calculate the urine volume non-invasively using these images. The BioCon-500™ is intended to be used only by qualified medical professionals. Contraindications for the BioCon-500™ are fetal use and use on pregnant patients.

7. Comparison with predicate device :

Mcube Technology Co., Ltd., believes that the BioCon-500 is substantially equivalent to the BVI 9400 of VERATHON INCORPORATED and Model M0001/M0002 of Mediwatch Ltd..

8. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard UL 60601-1 and IEC 60601-2-37 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and

based on the information provided in this premarket notification Mcube Technology Co., Ltd. concludes that The BioCon-500 is safe and effective and substantially equivalent to predicate devices as described herein.

10. Mcube Technology Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2009

Mcube Technology Co., Ltd.
% Mr. Marc M. Mouser
CAS Manager II / Office Coordinator
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

Re: K091518
Trade/Device Name: Diagnostic Ultrasound Systems and Accessories / CUBEscan BioCon-500
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: March 18, 2009
Received: May 22, 2009

Dear Mr. Mouser:

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 Diagnostic Ultrasound Systems and Accessories / CUBEscan BioCon-500, as described in your premarket notification:

Transducer Model Number

Ultrasound Probe of BioCon-500

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 Lauren Hefner at (240) 276-3666.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number(if known): K091518

Device Name: Diagnostic Ultrasound System and Accessories / **CUBEscan BioCon-500**

Indications for Use:

The **BioCon-500** is a B-mode pulsed-echo ultrasound device. The **BioCon-500** is intended to project ultrasound energy through the abdomen of the patient to obtain images of the bladder and to calculate the bladder volume non-invasively using these images. Contraindications for the **BioCon-500** are fetal use and use on pregnant patients.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 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 K091518

Diagnostic Ultrasound Indications For Use Form

System : BioCon-500 Diagnostic Ultrasound System with Accessories
Transducer : Ultrasound Probe of BioCon-500

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Bladder)	P						

N = new indication; P = previously cleared by FDA (K071217)