510(k) Summary

APR 27 2011

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

Data: Dec. 20, 2010

1. Company and Correspondent making the submission:

Name	:	Mcube Technology Co., Ltd.
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Contact	:	Mr. Seungtai Kim
Internet	:	http://www.mcubetech.co.kr

2. Device:

Trade/proprietary name	: CUBEscan BioCon-700
Common Name	: Diagnostic Ultrasound System with Accessories
Classification Name	: system, imaging, pulsed echo, ultrasonic

3. Predicative Device:

Manufacturer	: Verathon Inc.
Device	: BladderScan® BVI 9400
510(k) Number	: K071217(Decision Date – May 17, 2007)

Manufacturer	: Mcube Technology
Device	: CUBEscan / BioCon-500
510(k) Number	: K091518(Decision Date – June 18, 2009)

4. Classifications Names & Citations:

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

5. Description:

The BioCon-700 is a portable ultrasound system for measuring the urine volume in a patient. BioCon-700 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-700 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 build-in thermal printer after measurements right away. Also using the optional CubePro software, a user can review the scan results.

6. Indications for use:

The BioCon-700 is a B-mode pulsed-echo ultrasound device. The BioCon-700 is intended as a portable battery-operated device. The BioCon-700 projects ultrasonic energy through the abdomen of the patient obtaining images of the bladder in order to calculate the urine volume non-invasively. BioCon-700 is intended to be used by a qualified medical professional to non-invasively measure the urine volume in the bladder. Contraindications for the BioCon-700 are fetal use and use on pregnant patients.

7. Compatible with predicative device:

The BioCon-700 uses 2.6MHz mechanical sector probe. When a user initiates the scan the device rotates the ultrasound transducer, gets 12-plane B-mode images with 120 degrees sector view automatically and calculates bladder volume from the planes images. After the completion of the measurement the result is displayed on the LCD screen.

In the same manner predicative devices do take the same procedures when a user measures the bladder volume. The ultrasound power transmitted from the device is not user adjustable, and BioCon-700 is a Track 1 System and meets the FDA's pre-amendment acoustic output limits. So as the predicative devices are. Although there are some differences such as resonant frequency, acoustic power, power source and PC update, there is no significant differences in technological characteristics that affecting the safety and efficiency. These are evaluated by safety test and acoustic output test.

Feature	Proposed CUBEscan BioCon-700 Mcube Technology Co., Ltd.	Predicate CUBEscan BioCon-500 Mcube Technology Co., Ltd.	Predicate BladderScan® BVI 9400 Verathon, Inc.
FDA 510(k) Number	-	**K053325**	**K071217**
Indication for Use	The BioCon-700 is a B-mode pulsed-echo ultrasound device. The BioCon-700 is intended as a portable battery-operated device. The BioCon-700 projects ultrasonic energy through the abdomen of the patient obtaining images of the bladder in order to calculate the urine volume non-invasively. BioCon-700 is intended to be used by a qualified medical professional to non-invasively measure the urine volume in the bladder. Contraindications for the BioCon-700 are fetal use and use on pregnant patients.	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.	The BladderScan BVI 9400 is intended to project ultrasound energy through the lower abdomen of the non-pregnant patient to obtain an image of the bladder that is used to determine bladder volume noninvasively. The BladderScan BVI 9400 is contraindicated for fetal use and for use on pregnant patients.
Device classification name	System, Imaging, Pulsed Echo, Ultrasonic	System, Imaging, Pulsed Echo, Ultrasonic	System, Imaging, Pulsed Echo, Ultrasonic
Modes of operation	B mode	B mode	B mode
System Characteristics	- Portable - LCD Display & Control Button - Thermal Printer - Power source: Battery-operated or AD-DC adapter operated	- Portable - LCD Display & Control Button - Thermal Printer - Power source: Battery-operated	- Portable - LCD Display & Control Button - Thermal Printer - Power source: Battery-operated
Controls for change of acoustic output during scan	No	No	No
Transducer Type	Mechanical Sector Probe	Mechanical Sector Probe	Mechanical Sector Probe
Transducer	2.6 MHz	2.8 MHz	3.0 / 1.74 MHz

Feature	Proposed CUBEscan BioCon-700 Mcube Technology Co., Ltd.	Predicate CUBEscan BioCon-500 Mcube Technology Co., Ltd.	Predicate BladderScan® BVI 9400 Verathon, Inc.
FDA 510(k) Number	-	**K053325**	**K071217**
Resonant Frequency			
Number of elements	1	1	1
Transducer Diameter	10mm	14mm	13 mm
Sector Angle	120 degrees	120 degrees	120 degrees
Acoustic Output	- Maximum ultrasound I_{spta} during a scan: ≤1.0 mW/cm^2 - Maximum ultrasound I_{sppa} during a scan: ≤10.0 W/cm^2 - Maximum MI: 0.90 max	- Maximum ultrasound I_{spta} during a scan: ≤1.0 mW/cm^2 - Maximum ultrasound I_{sppa} during a scan: ≤10.0 W/cm^2 - Maximum MI: 0.90 max	- Maximum ultrasound I_{spta} during a scan: ≤5.0 mW/cm^2 - Maximum ultrasound I_{sppa} during a scan: ≤60.0 W/cm^2 - Maximum MI: 0.95 max
No of Scan Planes	12	12	12
FDA Limits	Track 1	Track 1	Track 1
Product Safety Certification	UL 60601-1, 1st Edition CAN/CSA-C22.2 No. 601.1-M90, 2005 EN 60601-2-37	UL 60601-1, 1st Edition CAN/CSA-C22.2 No. 601.1-M90, 2005 EN 60601-2-37	EN/IEC 60601-1 EN/IEC 60601-2-37 C22.2 No. 601.1-M90 UL 60601-1
EMC Compliance	EN 60601-1-2	EN 60601-1-2	EN/IEC 60601-1-2
Patient Contact Material	Plastic, PC (Model: HP1) (Skin Contact)	Plastic, PC (Model: HP1) (Skin Contact)	Plastic, Not Known (Skin Contact)
Accuracy	0~999: ±15%, ±15ml	0~999: ±15%, ±15ml	0~999: ±15%, ±15ml
Marketing History	Asia, Europe, Australia More than 50 devices	Asia, Europe, Australia More than 500 devices	Asia, Europe, Australia, North America, South America More than 300 devices
Real-time scanning	Yes (Pre-scan)	Yes (Pre-scan)	No
PC Software	Yes CubePro	Yes CubeScanPC	Yes ScanPoint
PC S/W function	Data Review Data Printing	Data Upload Data Review	Data Upload Data Review

Feature	Proposed CUBEscan BioCon-700 Mcube Technology Co., Ltd.	Predicate CUBEscan BioCon-500 Mcube Technology Co., Ltd.	Predicate BladderScan® BVI 9400 Verathon, Inc.
FDA 510(k) Number	-	**K053325**	**K071217**
		Data Printing	Data Printing
PC Data Upload	Using SD card	Using USB	BVI9400 to communication cradle: wireless Communication cradle to PC: USB
Accessories	Medical cart Battery pack	Medical cart Battery pack	Medical cart Battery pack

Mcube Technology Co., Ltd., believes that the BioCon-700 is substantially equivalent to the BVI 9400 of Verathon Incorporated and Model BioCon-500 of Mcube Technology Co., 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 IEC/EN 60601-1-2. All test results were satisfactory.

9. Conclusions:

The BioCon-700 was evaluated with safety (UL 60601-1 and IEC 60601-2-37), EMC (IEC/EN 60601-1-2), Biocompatibility (ISO10993-1, ISO 10993-5 and ISO 10993-10), Software (IEC 62304) and Acoustic Output (NEMA UD2).

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-700 is safe and effective and substantially equivalent to predicative devices as described herein.

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

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mcube Technology Co., Ltd.
% Mr. Marc M. Mouser
Engineering Leader & FDA Office Coordinator, Program Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

APR 27 2011

Re: K111021
Trade/Device Name: CUBEscan BioCon-700 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: March 28, 2011
Received: April 12, 2011

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 CUBEscan BioCon-700 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

BioCon-700 Transducer

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 Paul Hardy at (301) 796-6542.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known):

Device Name: Diagnostic Ultrasound System and Accessories / **CUBEscan BioCon-700**

Indications for Use:

The BioCon-700 is a B-mode pulsed-echo ultrasound device. The BioCon-700 is intended as a portable battery-operated device. The BioCon-700 projects ultrasonic energy through the abdomen of the patient obtaining images of the bladder in order to calculate the urine volume non-invasively. BioCon-700 is intended to be used by a qualified medical professional to non-invasively measure the urine volume in the bladder. Contraindications for the BioCon-700 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 In Vitro Diagnostic Devices (OIVD)

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

510K K111021

Diagnostic Ultrasound Indications For Use Form

System: CUBEscan BioCon-700 Diagnostic Ultrasound System
Transducer: BioCon-700 Transducer

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-urethreal							
	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; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Prescription Use (Per 21 CFR 801.109)

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

510K K111021