DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 22, 2017

Mcube Technology Co., Ltd.
% Mr. Dave Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
MILLBURN NJ 07041

Re: K171591
Trade/Device Name: CUBEScan™ BioCon-900 (Bladder Volume Measurement System)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: May 28, 2017
Received: June 1, 2017

Dear Mr. Yungvirt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indication for Use

From Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See *PRA* Statement below

510(k) Number *(if known)*

K171591

Device Name

CUBEScan™ BioCon-900 (Bladder Volume Measurement System)

Indications for use *(Describe)*

BioCon-900 is a B-mode pulsed-echo ultrasound device. The BioCon-900 projects ultrasonic energy through the lower abdomen of a patient to obtain images of the bladder to calculate the urine volume non-invasively. BioCon-900 is intended to be used by a qualified medical professional to non-invasively measure the urine volume in the bladder. Contraindications for the BioCon-900 are fetal use and use on pregnant patients.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) □ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARETE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Form

System: CUBEScan™ BioCon-900
Bladder Volume Measurement System
Transducer: BioCon-900
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	N						
	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)	P						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel							
	Other							

N = new indication; P = previously cleared by FDA in K111021; 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 devices (Part 21 CFR 801.109)

510(k) Summary

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

1) SUBMITTER

Submitter:	Mcube Technology Co., Ltd. #803, 123 Bonghwasan-ro, Jungnang-gu, Seoul, Korea
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Date Prepared:	Feb 15, 2016

2) DEVICE

Trade Name(s):	CUBEScan™ BioCon-900	
Common Name:	Bladder Volume Measurement System	
Classification:	II	
Classification Name(s):	Ultrasonic Pulsed Echo Imaging System	Diagnostic Ultrasound Transducer
Regulation Number:	21 CFR 892.1560	21 CFR 892.1570
Product Code:	IYO	ITX
Classification Panel:	Radiology	

3) PREDICATE DEVICE

Predicate Devices:	Mcube Technology Co., Ltd. CUBEScan™ BioCon-700	K111021

4) DEVICE DESCRIPTION

CUBEScan™ BioCon-900 (bladder volume measurement system) is a safe and easy, non-invasive system to measure the bladder volume. CUBEScan™ BioCon-900 is a B-mode instrument, hand-held, wireless and battery-operated. A 3D-mechnical sector transducer provides cross-sectional images of the bladder from up to 12 scan planes and bladder volume is calculated based upon those images and displays 12 scan planes on a screen. Furthermore, a live image of the bladder during Pre-Scan makes it easier to detect the bladder before scanning. Measurements are transmitted to a personal computer running CubePro software via a wireless connection. CubePro allows the user to print measurements, archive data and so on.

5) INTENDED FOR USE/INDICATIONS FOR USE

BioCon-900 projects ultrasonic energy through the lower abdomen of a patient to obtain images of bladder to calculate the urine volume non-invasively.

6) COMPARISION OF CUBEscan™ BioCon-900 WITH THE PREDICATE DEVICES

The CUBEScan™ BioCon-900 is substantially equivalent to the currently marketed BioCon-700.

The subject and the predicate devices are based on the following same technological elements:

- Intended use: Projection of ultrasonic energy into the abdomen of patients.
- Patient population and anatomical site
- Measurement of bladder volume
- Accuracy of measurement
- Mode of operation
- Transducer type, sector angle, number of element and number of scan planes
- Acoustic output intensity
- Displays, portable, button controls, attached printer and PC software for data management
- Standards of safety, EMC, biocompatibility

The following technological differences exist between the CUBEScan™ BioCon-900 and predicate devices.

- Transducer resonant frequency
- Patient contact material
- Transducer diameter
- Charger
- Data Transmission tools(Touch screen operation and accessories)
- Input of information
- PC program version

7) Summary of Non-Clinical Testing Performed

The following performance data were provided in support of the substantial equivalence

Biocompatibility Testing
The biocompatibility test for CUBEScan™ BioCon-900 was conducted in accordance with ISO-10993 as recognized by FDA. The following tests performed:
- Cytotoxicity Test (MEM Elution Test)
- Maximization Sensation
- Intracutaneous Reactivity

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were conducted on the CUBEScan™ BioCon-900. The CUBEScan™ BioCon-900 complied with AAMI/ANSI ES 6060-1, IEC6060-1-2 for safety and EMC including battery, Ir communication, barcode and wireless charging.

Acoustic Output Testing
The acoustic output test for was CUBEScan™ BioCon-900 conducted in accordance with IEC60601-2-37.

Software Validation
Software Validation testing for CUBEScan™ BioCon-900 was conducted and documentation was provided as recommended "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Volume Measuring Testing
In order to demonstrate the accuracy of CUBEScan™ BioCon-900, a tissue-equivalent bladder phantom with a balloon which has a designated volume is used. The accuracy has been demonstrated by designated volume to the volume from CUBEScan™ BioCon-900.

Wireless Telecommunication & Charging
The CUBEScan™ BioCon-900 is intended for use in an environment in which radiated RF disturbances are controlled. In order to demonstrate the safety of RF communications, Wireless Telecommunication Testing was conducted in accordance with 47 CFR FCC – Telecommunications, Chapter I - Federal Communications Commission, Subchapter A – General Part 15 – Radiofrequency Devices Subpart C section 15.207/15.209 and RF Exposure

8) 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 CUBEScan™ BioCon-900 is safe and effective and substantially equivalent to predicative devices as described herein.

END of 510(k) Summary