



Mcube Technology Co., Ltd.  
% Hye-Ri Choi  
RA Manager  
#803, 123, Bonghwasan-ro, Jungnang-gu  
Seoul, 02048  
REPUBLIC OF KOREA

August 19, 2020

Re: K201995  
Trade/Device Name: CUBEScan BioCon-1100  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulatory Class: Class II  
Product Code: IYO, ITX  
Dated: July 17, 2020  
Received: July 20, 2020

Dear Hye-Ri Choi:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.  
Director  
Division of Radiological Health  
OHT7: Office of In Vitro Diagnostics  
and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K201995

Device Name

CUBEScan BioCon-1100

Indications for Use (Describe)

The CUBEScan BioCon-1100 is a B-mode pulsed-echo ultrasound device. The BioCon-1100 projects ultrasonic energy through the lower abdomen of a patient to obtain images of the bladder to calculate the urine volume non-invasively. The BioCon-1100 is intended to be used by a qualified medical professional in hospitals and other healthcare facilities to non-invasively measure the urine volume in the bladder. Contraindications for the BioCon-1100 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 SEPARATE PAGE IF NEEDED.

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## 510(k) Summary K201995

The following summary of information is provided in accordance with requirements of 21 CFR 807.92.

### 1) SUBMITTER

510(k) (Manufacturer)	Owner	Mcube Technology Co., Ltd. #803, 123 Bonghwasan-ro, Jungnang-gu, Seoul, 02048 Korea Phone: +82 2 3421 7780 Fax: +82 2 3421 7076 E-mail: <a href="mailto:mcube@mcubetech.co.kr">mcube@mcubetech.co.kr</a>
Contact Person:		Hye-Ri Choi Assist Manager, Regulatory Affairs Phone: +82 2 3421 7780 E-mail: <a href="mailto:chr@mcubetech.co.kr">chr@mcubetech.co.kr</a>
Alternative Contact Person:		Chang-Hyun Kim Manager, QMR E-mail: <a href="mailto:kch@mcubetech.co.kr">kch@mcubetech.co.kr</a>
Date Prepared:		July 17, 2020

### 2) SUBJECT DEVICE

Trade/Proprietary Name:	CUBEScan BioCon-1100
Common/Usual Name:	Bladder Scanner, Bladder volume Measurement System
Product Code/ Regulation Number/ Classification Names	Main code: IYO, 892.1560, Ultrasonic Pulsed Echo Imaging System Secondary code: ITX, 892.1570, Diagnostic Ultrasonic Transducer
Classification Panel	Radiology

### 3) PREDICATE DEVICE

Predicate Devices:	CUBEScan BioCon-1100 (K200548, IYO, ITX)
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### 4) DEVICE DESCRIPTION

The CUBEScan BioCon-1100 (Bladder volume measurement system) is a safe, easy to use, non-invasive system for measuring bladder volume (residual volume). The CUBEScan BioCon-1100 is a B-mode ultrasound device, which consists of a probe that sends and receives ultrasonic waves, and a console that processes ultrasonic signals and converts them into the desired data. The 3D-mechanical sector transducer take the bladder in 12 sections and calculate the volume of the bladder based on the images which appear on the LCD screen. In addition, the pre-scan function allows users to easily locate the location of the bladder before scanning, making measurement easier.

Measurement results can be transferred to a computer, and data can be managed using CubePro-1100.

## **5) INTENDED FOR USE/INDICATIONS FOR USE**

The CUBEScan BioCon-1100 is a B-mode pulsed-echo ultrasound device. The BioCon-1100 projects ultrasonic energy through the lower abdomen of a patient to obtain images of the bladder to calculate the urine volume non-invasively. The BioCon-1100 is intended to be used by a qualified medical professional in hospitals and other healthcare facilities to non-invasively measure the urine volume in the bladder. Contraindications for the BioCon-1100 are fetal use and use on pregnant patients.

## **6) COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The technical characteristics in the new device is the same as that of the predicate device and the differences from the predicate device are as below;

- 1) Change of operating system (Linux) of console
- 2) Change of graphical user interfaces (GUIs) of console
- 3) Change of graphical user interfaces(GUIs) of CubePro (PC Program)
- 4) Change of height and width of rolling cart (MRC-1100).
- 5) Change of IPX degree

## **7) Summary of Non-Clinical Testing Performed**

The device has been evaluated for acoustic output, biocompatibility as well as thermal, electrical, electromagnetic and mechanical safety and have been found to conform to applicable medical device safety standards and guidance documents.

## **8) Summary of Clinical Tests**

The subject of this premarket submission, CUBEScan BioCon-1100, did not require clinical studies to support substantial equivalence.

## **9) Conclusions**

The new addition of Linux Operating System and change the liquid safety level to IPX 5 do not affect the device performance characteristics and does not change the device Indication for use.

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-1100 to be as safe, as effective, and performance is substantially equivalent to the predicative devices.

END of 510(k) Summary

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