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

May 19, 2020

Re: K200749
Trade/Device Name: CUBEScan BioCon-900S
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: March 20, 2020
Received: March 23, 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 and Part 809); 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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200749

Device Name
CUBEScan BioCon-900S

Indications for Use *(Describe)*
The CUBEScan BioCon-900S is a B-mode pulsed-echo ultrasound device. The BioCon-900S 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-900S 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-900S 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.**

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.***

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# 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) APPLICANT INFORMATION

| | |
|---|---|
| 510(k) Owner (Manufacturer) | Mcube Technology Co., Ltd.<br>#803, 123 Bonghwasan-ro,<br>Jungnang-gu, Seoul, 02048 Korea<br>Phone: +82 2-3421 7780<br>Fax: +82 2 3421 7076<br>E-mail: mcube@mcubetech.co.kr |
| Contact Person: | Hye-Ri Choi<br>Assist Manager, Regulatory Affairs<br>Phone: +82 2 3421 7780<br>E-mail: chr@mcubetech.co.kr |
| Alternative Contact Person: | Chang-Hyun Kim<br>Manager, QMR<br>E-mail: kch@mcubetech.co.kr |
| Date Prepared: | March 20, 2020 |

## 2) SUBJECT INFORMATION

| | |
|---|---|
| Trade/Proprietary Name: | CUBEScan BioCon-900S |
| 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<br>Secondary code: ITX, 892.1570, Diagnostic Ultrasonic Transducer |
| Classification Panel | Radiology |

## 3) PREDICATE DEVICE

| | |
|---|---|
| Predicate Devices: | CUBEScan BioCon-900 (K171591, IYO, ITX) |

## 4) DEVICE DESCRIPTION

CUBEScan BioCon-900S is a safe and easy, non-invasive system to measure the bladder volume. The device consists of a probe and various components. The probe is a B-mode instrument, which is hand-held, wireless and battery-operated. A 3D-mechanical sector transducer provides cross–sectional images of the bladder from up to 12 scan planes which users can check through the screen and bladder volume is calculated based upon those images. In addition, the Pre-scan function allows users to easily locate the bladder before scanning, making measurement easier. CUBEScan BioCon-900S consists of a probe and CUBEscan Charger or a probe and CUBEScan Docking Station, with an optional mobile cart and a barcode module.

- **CUBEScan Charger** is used to recharge the probe's internal battery.

- **CUBEScan Docking Station** is used to recharge the probe's internal battery, transfer scan results to a PC which can run CubePro-900S (PC software for data processing), and print a scan results with installed thermal printer.

## 5) INTENDED FOR USE/INDICATIONS FOR USE

The CUBEScan BioCon-900S is a B-mode pulsed-echo ultrasound device. The BioCon-900S 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-900S 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-900S are fetal use and use on pregnant patients.

## 6) COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics are substantially equivalent to the predicate device (K171591) based on the same indications for use, the same fundamental scientific technology.

## 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.

The CUBEScan BioCon-900S comply with the following safety standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2: 2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60601-2-37:2007+A1:2015, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasound medical diagnostic and monitoring equipment.
- ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- AIUM/NEMA UD-2:2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
- ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
- IEC 62359: 2017 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- IEC 60825-1:2007 Safety of laser products – Part 1 : Equipment classification and requirements

Miscellaneous Standards:

- IEC 60601-1-6:2013 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- ANSI AAMI IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- AAMI ANSI HE75 Human Factors Engineering – Design of medical devices 2009/(R)2013

## 8) Summary of Clinical Tests

The subject of this premarket submission, CUBEScan BioCon-900S, did not require clinical studies to support substantial equivalence.

## 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 CUBEScan BioCon-900S to be as safe, as effective, and performance is substantially equivalent to the predicative devices.

END of 510(k) Summary