Mcube Technology Co., Ltd.
℅ Mr. Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd.
WARREN NJ 07059

March 27, 2020

Re: K200548
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: February 28, 2020
Received: March 3, 2020

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. 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) 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)*
K200548

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.

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

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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) SUBMITTER

510(k) Owner (Manufacturer)	Mcube Technology Co., Ltd. #803, 123 Bonghwasan-ro, Jungnang-gu, Seoul, Korea Phone: +82 2-3421 7780 Fax: +82 2 3421 7076 E-mail: mcube@mcubetech.co.kr
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Date Prepared:	Feb 15, 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-900 (K171591, IYO, ITX)

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) COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics are substantially equivalent to that of the predicate.

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

- The material of patient contact
- Mode of operation;
- Acoustic Output

The following technological differences exist between the CUBEScan™ BioCon-1100 and predicate devices.

- Transducer resonant frequency
- Measurement Accuracy

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-1100 comply with the following standards:

- ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment, Part 1: General requirements for safety IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012)
- IEC 60601-1-2: 2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - 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.
- AIUM/NEMA UD-2:2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
- ISO 10993-1 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)]
- 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.
- ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
- 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

The CUBEScan™ BioCon-1100 comply with the following guidance:

- Guidance for Industry and FDA Staff – Marketing Clearance of Diagnostic Systems and Transducers (June 27, 2019)
- General Principles of Software Validation (Jan 11, 2002)
- Guidance for the Content and Premarket Submission for Software Contained in Medical Devices (May 11, 2005)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, (Oct 2, 2014)

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

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