

K171591 CUBEScan™ BioCon-900 (Bladder Volume Measurement System)Jun 22, 2017
22 days to decisionK171591 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k171591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	May 31, 2017
Decision date	Jun 22, 2017
Days to decision	22 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Mcube Technology Co., Ltd.
Location	Flintville, TN, US
Contact	Changhyun Kim
510(k) history	6 submissions · 6 cleared · 2009-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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