

K200548 CUBEScan BioCon-1100Mar 27, 2020
24 days to decisionK200548 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k200548/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Mar 3, 2020
Decision date	Mar 27, 2020
Days to decision	24 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	DAVE YUNGVIRT

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200548/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 15, 2026