

K201995 CUBEScan BioCon-1100Aug 19, 2020
30 days to decisionK201995 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k201995/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jul 20, 2020
Decision date	Aug 19, 2020
Days to decision	30 days
Third-party review	No
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

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