FDA 510(k) Premarket Notification

K133641 CORE CONTROL PAD, CORE SERIES SW V3.4 INSTALLATION KIT, CORE, CORE MOBILE

CLEARED

Dec 20, 2013
23 days to decision

K133641 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k133641/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 27, 2013
Decision date	Dec 20, 2013
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Volcano Corporation**
Location	Rancho Cordova,, CA, US
Contact	MARCUS GARCIA
510(k) history	55 submissions · 55 cleared · 2005-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k133641/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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