FDA 510(k) Premarket Notification

K162440 CardioInsight Cardiac Mapping System

CLEARED

Nov 4, 2016
65 days to decision

K162440 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k162440/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Aug 31, 2016
Decision date	Nov 4, 2016
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardioinsight Technologies, Inc.**
Location	Cleveland, OH, US
Contact	LAURIE LEWANDOWSKI
510(k) history	3 submissions · 3 cleared · 2014-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k162440/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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