FDA 510(k) Premarket Notification

K133534 MCKESSON CARDIOLOGY ECG MOBILE

CLEARED

Apr 18, 2014
151 days to decision

K133534 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k133534/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Nov 18, 2013
Decision date	Apr 18, 2014
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mckesson Israel , Ltd.**
Location	Tel Aviv, IL
Contact	PAUL SUMNER
510(k) history	5 submissions · 5 cleared · 2012-2015