FDA 510(k) Premarket Notification

K131497 MCKESSON CARDIOLOGY HEMO

CLEARED

Dec 5, 2013
195 days to decision

K131497 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k131497/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	May 24, 2013
Decision date	Dec 5, 2013
Days to decision	195 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k131497/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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