FDA 510(k) Premarket Notification

K131854 CEROX

CLEARED

Sep 13, 2013
84 days to decision

K131854 · Product code: **DPW** · Cardiovascular
Source: https://www.510kdatabase.net/k131854/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Jun 21, 2013
Decision date	Sep 13, 2013
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Or-Nim Medical , Ltd.**
Location	Washington, DC, US
Contact	MICHA OESTEREICH
510(k) history	5 submissions · 5 cleared · 2008-2015