FDA 510(k) Premarket Notification

K030357 QUANTIX/OR DEVICE

CLEARED

Aug 20, 2003
198 days to decision

K030357 · Product code: **DPW** · Cardiovascular
Source: https://www.510kdatabase.net/k030357/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Feb 3, 2003
Decision date	Aug 20, 2003
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiosonix, Ltd.**
Location	Kfar Saba, IL
Contact	AHAVA STEIN
510(k) history	3 submissions · 3 cleared · 2002-2004