

K030357 QUANTIX/OR DEVICEAug 20, 2003
198 days to decisionK030357 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030357/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026