

K132545 MEDIVALVE ACWIRENov 8, 2013
87 days to decisionK132545 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k132545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 13, 2013
Decision date	Nov 8, 2013
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medivalve , Ltd.
Location	Providence, RI, US
Contact	LEO BASTA
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132545/> 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 8, 2026