

K120349 SONIXGPS VASCULAR ACCESS NEEDLE KITApr 9, 2012
63 days to decisionK120349 · Product code: **DRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k120349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Feb 6, 2012
Decision date	Apr 9, 2012
Days to decision	63 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Ultrasonix Medical Corpation
Location	Richmond, CA
Contact	CHAS YU
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120349/> 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 15, 2026