FDA 510(k) Premarket Notification

K120349 SONIXGPS VASCULAR ACCESS NEEDLE KIT

CLEARED

Apr 9, 2012
63 days to decision

K120349 · 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