FDA 510(k) Premarket Notification

K122659 VDRIVE W/V-SONO

CLEARED

Jul 26, 2013
329 days to decision

K122659 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k122659/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 31, 2012
Decision date	Jul 26, 2013
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stereotaxis, Inc.**
Location	St. Louis, MO, US
Contact	HORWITZ
510(k) history	28 submissions · 28 cleared · 2002-2026