

K150312 Vdrive system, Vdrive Duo, Vdrive with V-SonoJun 17, 2015
128 days to decisionK150312 · Product code: **DXX** · CardiovascularSource: <https://www.510kdatabase.net/k150312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Catheter Control, Steerable (DXX)
Date received	Feb 9, 2015
Decision date	Jun 17, 2015
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stereotaxis, Inc.
Location	St. Louis, MO, US
Contact	JOHN NADELIN
Website	https://www.stereotaxis.com
510(k) history	28 submissions · 28 cleared · 2002-2026

Stereotaxis, Inc. is a pioneer and global leader in innovative surgical robotics for minimally invasive endovascular intervention. The company develops robotic systems, instruments, and information solutions for the interventional laboratory. Stereotaxis operates with a manufacturing facility in St. Louis, Missouri. The company has received FDA 510(k) clearances from total submissions, with no denied submissions on record. Cardiovascular devices represent 89% of the company's regulatory portfolio. Stereotaxis has maintained continuous FDA 510(k) activity since its first c...
