

K043457 MODIFICATION TO ENDOVASCULAR GUIDE WIREFeb 28, 2005
75 days to decisionK043457 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k043457/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 15, 2004
Decision date	Feb 28, 2005
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stereotaxis, Inc.
Location	St. Louis, MO, US
Contact	GARY RAUVOLA
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...
