

**K060967 NIOBE MAGNETIC NAVIGATION SYSTEM
W/NAVIGANT WORKSTATION**Oct 19, 2006
195 days to decisionK060967 · Product code: **NDQ** · Neurology
Source: <https://www.510kdatabase.net/k060967/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Catheter Or Guidewire, Steerable (magnetic) (NDQ)
Date received	Apr 7, 2006
Decision date	Oct 19, 2006
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stereotaxis, Inc.
Location	St. Louis, MO, US
Contact	DENNIS POZZO
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...

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