FDA 510(k) Premarket Notification

K051373 CRONUS GUIDEWIRE, MODEL 001-001470-1

CLEARED

Dec 9, 2005
197 days to decision

K051373 · Product code: **NDQ** · Neurology
Source: https://www.510kdatabase.net/k051373/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Catheter Or Guidewire, Steerable (magnetic) (NDQ)
Date received	May 26, 2005
Decision date	Dec 9, 2005
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stereotaxis, Inc.**
Location	St. Louis, MO, US
Contact	KELLY ROWLAND
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...