

**K042850 CARDIODRIVE, MODEL 001-004115 (NON-STERILE)**Aug 9, 2006  
663 days to decisionK042850 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k042850/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 15, 2004
Decision date	Aug 9, 2006
Days to decision	663 days
Third-party review	No
Summary / Statement	Summary
Other names	001-1169-1 (STERILE)

**APPLICANT**

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Company	<b>Stereotaxis, Inc.</b>
Location	St. Louis, MO, US
Contact	GARY RAUVOLA
Website	<a href="https://www.stereotaxis.com">https://www.stereotaxis.com</a>
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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