

**K072371 ODYSSEY WORKSTATION**Nov 14, 2007  
83 days to decisionK072371 · Product code: **DXX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k072371/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Catheter Control, Steerable (DXX)
Date received	Aug 23, 2007
Decision date	Nov 14, 2007
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stereotaxis, Inc.</b>
Location	St. Louis, MO, US
Contact	DENNIS POZZO
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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