

K113628 AMIGO REMOTE CATHETER SYSTEM (RCS) & ACCESSORIESJun 12, 2012
187 days to decisionK113628 · Product code: **DXX** · Cardiovascular
Source: <https://www.510kdatabase.net/k113628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Catheter Control, Steerable (DXX)
Date received	Dec 8, 2011
Decision date	Jun 12, 2012
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Catheter Robotics, Inc.
Location	Mount Olive, NJ, US
Contact	JENNIFER ENGLUND
510(k) history	3 submissions · 2 cleared · 2012-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113628/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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