

**K131079 CREGANNA-TACTX STEERABLE SHEATH SET
SYMMETRIC**Aug 1, 2013
106 days to decisionK131079 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k131079/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 17, 2013
Decision date	Aug 1, 2013
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Creganna Medical Devices
Location	Northborough, MA, US
Contact	CHRISTINE NICHOLS
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131079/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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