

**K140338 CREGANNA TACTX LOTUS INTRODUCER SET  
(SMALL), CREGANNA TACTX LOTUS INTRODUCER SET  
(LARGE)**Aug 27, 2014  
198 days to decisionK140338 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k140338/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Feb 10, 2014
Decision date	Aug 27, 2014
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Creganna-Tactx Medical</b>
Location	Campbell, CA, US
Contact	NIALL FOX
510(k) history	2 submissions · 2 cleared · 2011-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140338/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 6, 2026