

**K153311 Flexitouch System**Sep 14, 2016  
302 days to decisionK153311 · Product code: **PPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k153311/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Head And Neck, Compressible (PPS)
Date received	Nov 17, 2015
Decision date	Sep 14, 2016
Days to decision	302 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tactile Systems Technology, Inc. (Dba Tactile Medical)</b>
Location	Minneapolis, MN, US
Contact	Thomas A Dold
510(k) history	3 submissions · 3 cleared · 2016-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153311/> 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 28, 2026