

**K122048 COLLAGEN TENDON SHEET-D**Jan 8, 2013  
180 days to decisionK122048 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k122048/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Jul 12, 2012
Decision date	Jan 8, 2013
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rotation Medical, Inc.</b>
Location	Plymouth, MN, US
Contact	JEFF SIMS
510(k) history	5 submissions · 5 cleared · 2011-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122048/> 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 May 14, 2026