

**K162934 Biodesign Parastomal Hernia Repair Graft**Jul 10, 2017  
263 days to decisionK162934 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162934/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Oct 20, 2016
Decision date	Jul 10, 2017
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Biotech Incorporated</b>
Location	West Lafayette, IN, US
Contact	Perry W. Guinn
510(k) history	16 submissions · 16 cleared · 2013-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162934/> 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 26, 2026