

**K110402 BIODESIGN NIPPLE RECONSTRUCTION CYLINDER**Jun 20, 2011  
129 days to decisionK110402 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k110402/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Feb 11, 2011
Decision date	Jun 20, 2011
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Biotech, Inc.</b>
Location	West Lafayette, IN, US
Contact	PERRY W GUINN
510(k) history	31 submissions · 31 cleared · 1998-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110402/> 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