

**K980431 SURGISIS**May 28, 1998  
113 days to decisionK980431 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k980431/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Feb 4, 1998
Decision date	May 28, 1998
Days to decision	113 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	NEAL E FEARNOTM PH.D
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/k980431/> 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