

**K161221 Biodesign Sling, Biodesign Plastic Surgery Matrix,
Biodesign Anal Fistula Plug**May 26, 2016
27 days to decisionK161221 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161221/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical (FTM)
Date received	Apr 29, 2016
Decision date	May 26, 2016
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161221/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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