

K170016 Biodesign Fistula PlugJun 21, 2017
169 days to decisionK170016 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k170016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Jan 3, 2017
Decision date	Jun 21, 2017
Days to decision	169 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

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