

K150668 Biodesign Enterocutaneous Fistula PlugDec 9, 2015
268 days to decisionK150668 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k150668/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Mar 16, 2015
Decision date	Dec 9, 2015
Days to decision	268 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	4 submissions · 4 cleared · 2013-2015

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