

K171817 Biodesign Diaphragmatic Hernia GraftMar 13, 2018
267 days to decisionK171817 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k171817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Jun 19, 2017
Decision date	Mar 13, 2018
Days to decision	267 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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