

**K160869 Biodesign Tissue Graft, Biodesign Dural Graft,
Biodesign Peyronie's Repair Graft**Apr 29, 2016
30 days to decisionK160869 · Product code: **FTM** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k160869/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical (FTM)
Date received	Mar 30, 2016
Decision date	Apr 29, 2016
Days to decision	30 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/k160869/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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