

**K191696 Biodesign Anal Fistula Plug, Biodesign Fistula Plug,
Biodesign Plastic Surgery Matrix, Biodesign Tissue Graft**Dec 27, 2019
185 days to decisionK191696 · Product code: **OXN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191696/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Collagen, Fistula (OXN)
Date received	Jun 25, 2019
Decision date	Dec 27, 2019
Days to decision	185 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/k191696/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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