

K170945 Biodesign Staple Line ReinforcementApr 28, 2017
29 days to decisionK170945 · Product code: **OXE** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k170945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Collagen, Staple Line Reinforcement (OXE)
Date received	Mar 30, 2017
Decision date	Apr 28, 2017
Days to decision	29 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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