

K201000 Biodesign Staple Line ReinforcementJul 13, 2020
88 days to decisionK201000 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Apr 16, 2020
Decision date	Jul 13, 2020
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Biotech Incorporated
Location	West Lafayette, IN, US
Contact	Nick Wang
510(k) history	16 submissions · 16 cleared · 2013-2024

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