

K163197 Cook Holmium Laser FiberMay 24, 2017
190 days to decisionK163197 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k163197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 15, 2016
Decision date	May 24, 2017
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Colin Jacob
510(k) history	175 submissions · 153 cleared · 2006-2024

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