

K193600 EndoGI Biliary Stent SystemJun 26, 2020
186 days to decisionK193600 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k193600/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 23, 2019
Decision date	Jun 26, 2020
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Endogi Medical, Ltd.
Location	Nazareth, IL
Contact	Omri Naveh
510(k) history	2 submissions · 1 cleared · 2020-2023

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