

**K251658 Endoflux™ Biliary & Pancreatic Stent Sets**Apr 16, 2026  
321 days to decisionK251658 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k251658/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	May 30, 2025
Decision date	Apr 16, 2026
Days to decision	321 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medi-Globe GmbH</b>
Location	Achenmuehle, DE
Contact	Stephan Schneider
510(k) history	1 submissions · 1 cleared · 2026-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251658/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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