

K251229 EndoFix™ Tissue Fixation SystemAug 20, 2025
121 days to decisionK251229 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k251229/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 21, 2025
Decision date	Aug 20, 2025
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Softac Medical Technologies
Location	Plainville, MA, US
Contact	Rickey Hart
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251229/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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