

**K253987 BARE Wireguided Balloon Dilation Catheter (1235)**Mar 13, 2026  
91 days to decisionK253987 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k253987/>**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	Dec 12, 2025
Decision date	Mar 13, 2026
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>GIE Medical</b>
Location	Brooklyn Park, MN, US
Contact	Ian Schorn
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQM+</b>
Contact	Gabriela Molnar

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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