

**K251170 Tangent Single-Use Digital System: Tangent Single-Use Digital Catheter and Tangent Digital Controller**Sep 12, 2025  
150 days to decisionK251170 · Product code: **FBN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k251170/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Choledochoscope And Accessories, Flexible/rigid (FBN)
Date received	Apr 15, 2025
Decision date	Sep 12, 2025
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tangent Endoscopy, LLC</b>
Location	Camden, DE, US
Contact	Daniel Amendola
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>TAG3 Engineering</b>
Contact	Diane Horwitz

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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