

**K231422 Precision GI**Aug 28, 2023  
103 days to decisionK231422 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k231422/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	May 17, 2023
Decision date	Aug 28, 2023
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Limaca Medical, Ltd.</b>
Location	En Ha&apos;Emeq, IL
Contact	Assaf Klein
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sfadc, LLC</b>
Contact	Susan Alpert

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231422/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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