FDA 510(k) Premarket Notification

# K231422 Precision GI

**CLEARED**

Aug 28, 2023
103 days to decision

K231422 · Product code: **FCG** · Gastroenterology & Urology
Source: 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

| | |
|---|---|
| Company | **Limaca Medical, Ltd.** |
| Location | En Ha'Emeq, IL |
| Contact | Assaf Klein |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Sfadc, LLC** |
| Contact | Susan Alpert |

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