

**K221085 LiNA OperaScope Needle**Sep 2, 2022  
142 days to decisionK221085 · Product code: **FBK** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k221085/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Apr 13, 2022
Decision date	Sep 2, 2022
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lina Medical Aps</b>
Location	Chapel Hill, NC, US
Contact	Jaroslav Mrówczyński
510(k) history	16 submissions · 16 cleared · 2006-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>MEDlcept, Inc.</b>
Contact	Scott Blood

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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