

K240227 LiNA CystoVu™ HD (CYV-100-5)Aug 22, 2024
209 days to decisionK240227 · Product code: **FAJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k240227/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Jan 26, 2024
Decision date	Aug 22, 2024
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CYV-101-5); LiNA ScopeVu™ (SCP-100-1)

APPLICANT

Company	Lina Medical Aps
Location	Chapel Hill, NC, US
Contact	Barczak Katarzyna
510(k) history	16 submissions · 16 cleared · 2006-2024

REGULATORY CONSULTANT

Consulting firm	MEDIcept, Inc.
Contact	Richelle Helman

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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