

**K193007 LiNA OperaScope with HDMI cable and on-board LCD -
6 units, LiNA OperaScope Recording Module**Jan 17, 2020
81 days to decisionK193007 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k193007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Oct 28, 2019
Decision date	Jan 17, 2020
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193007/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026