

**K171113 LiNA OperaScope with HDMI cable and on-board LCD-single unit, LiNA OperaScope with HDMI cable and on-board LCD-6 units, LiNA OperaScope Recording Module**Jan 4, 2018  
265 days to decisionK171113 · Product code: **HIH** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k171113/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Hysteroscope (and Accessories) (HIH) |
| Date received         | Apr 14, 2017                         |
| Decision date         | Jan 4, 2018                          |
| Days to decision      | 265 days                             |
| Third-party review    | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171113/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026