

**K112357 VESSEL GUARDIAN**Nov 10, 2011  
86 days to decisionK112357 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k112357/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Aug 16, 2011
Decision date	Nov 10, 2011
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lexion Medical, LLC</b>
Location	St. Paul, MN, US
Contact	BERNARD HORWATH
510(k) history	13 submissions · 13 cleared · 2007-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112357/> 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 June 20, 2026