

K091366 INSUFLOW DEWHEARTSep 3, 2009
118 days to decisionK091366 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k091366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	May 8, 2009
Decision date	Sep 3, 2009
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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