

K153513 Insufflator 50L FM134Mar 4, 2016
88 days to decisionK153513 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k153513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Dec 7, 2015
Decision date	Mar 4, 2016
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W.O.M. World of Medicine GmbH
Location	Tucson, AR, US
Contact	Soeren Markworth
510(k) history	26 submissions · 26 cleared · 1992-2025

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