

**K222812 Insufflator**May 16, 2023  
239 days to decisionK222812 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k222812/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Sep 19, 2022
Decision date	May 16, 2023
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Scivita Medical Technology Co., Ltd.</b>
Location	Suzhou, CN
Contact	Ruqin Wu
510(k) history	12 submissions · 12 cleared · 2019-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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