

K252318 Insufflator (OPTO-IFL1000)Apr 16, 2026
265 days to decisionK252318 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k252318/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Jul 25, 2025
Decision date	Apr 16, 2026
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Optomedic Technologies, Inc.
Location	Foshan, CN
Contact	Weijuan Guo
510(k) history	9 submissions · 9 cleared · 2023-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252318/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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