

K231342 Insufflator (OPTO-IFL1000)Sep 20, 2023
134 days to decisionK231342 · Product code: **HIF** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k231342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	May 9, 2023
Decision date	Sep 20, 2023
Days to decision	134 days
Third-party review	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

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