

K232401 Disposable Veress NeedlesDec 14, 2023
126 days to decisionK232401 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k232401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Aug 10, 2023
Decision date	Dec 14, 2023
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou Kangji Medical Instrument Co., Ltd.
Location	Hangzhou, CN
Contact	Martin Sun
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai Lingfu Technology Co., Ltd.
Contact	Esther Zhang

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

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