FDA 510(k) Premarket Notification

K222812 Insufflator

CLEARED

May 16, 2023
239 days to decision

K222812 · Product code: **HIF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k222812/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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