

K250939 SIRIUS Endoscope System (PR-SI-1230)Aug 29, 2025
154 days to decisionK250939 · Product code: **HET** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k250939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Mar 28, 2025
Decision date	Aug 29, 2025
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Precision Robotics (Hong Kong) Limited
Location	Hong Kong, CN
Contact	Alan Kwok
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Vee Care Asia Limited
Contact	Kacia Mak

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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