

**K221642 SIRIUS Endoscope System**Dec 12, 2022  
189 days to decisionK221642 · Product code: **HET** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k221642/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Jun 6, 2022
Decision date	Dec 12, 2022
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Precision Robotics (Hong Kong) Limited</b>
Location	Hong Kong, CN
Contact	Ping Lai Benny Lo
510(k) history	2 submissions · 2 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Vee Care (Asia) Limited</b>
Contact	Sharon Hsu

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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