

K243867 LAGIS Suction Irrigation SystemMar 17, 2025
90 days to decisionK243867 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243867/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 17, 2024
Decision date	Mar 17, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lagis Enterprise Co., Ltd.
Location	Taichung City, TW
Contact	Lynn Chen
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243867/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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