

K253994 TroKit Laparoscope Lens WiperJun 4, 2026
174 days to decisionK253994 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 12, 2025
Decision date	Jun 4, 2026
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	TroCare, LLC
Location	Houston, TX, US
Contact	Gerald Sanders
510(k) history	2 submissions · 2 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	QSR Consulting
Contact	Kenneth Kleinhenz

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253994/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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