

K241842 Luer-Split MAJ-2092Mar 19, 2025
266 days to decisionK241842 · Product code: **ODC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k241842/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Jun 26, 2024
Decision date	Mar 19, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Medical Systems Corporation
Location	Melville, NY, US
Contact	Shinichiro Kawachi
510(k) history	81 submissions · 81 cleared · 2004-2026

REGULATORY CONSULTANT

Consulting firm	Olympus Surgical Technologies of America
Contact	Rebecca Walker

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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