

**K243502 EVIS EUS ENDOSCOPIC ULTRASOUND CENTER
OLYMPUS EU-ME3 (OLYMPUS EU-ME3)**Jan 17, 2025
66 days to decisionK243502 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k243502/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 12, 2024
Decision date	Jan 17, 2025
Days to decision	66 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	Toshio Nakamura
510(k) history	81 submissions · 81 cleared · 2004-2026

REGULATORY CONSULTANT

Consulting firm	Olympus Surgical Technologies of the Americas
Contact	Wendy Perreault

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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