

K250949 Suction Valve (MAJ-1443)Jul 16, 2025
110 days to decisionK250949 · Product code: **ODC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250949/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Mar 28, 2025
Decision date	Jul 16, 2025
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Air/Water Valve (MAJ-1444)

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Olympus Corporation of the Americas
Contact	Susan Lewandowski

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250949/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026