

**K251997 Single-Use Biopsy Valve (MAJ-1555)**Sep 25, 2025  
90 days to decisionK251997 · Product code: **OCX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k251997/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Irrigation/suction System (OCX)
Date received	Jun 27, 2025
Decision date	Sep 25, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Olympus Medical Systems Corporation</b>
Location	Melville, NY, US
Contact	Jillian Connery
510(k) history	81 submissions · 81 cleared · 2004-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251997/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026