

**K250883 ULTRASONIC PROBE UM-3R (UM-3R)**Sep 18, 2025  
178 days to decisionK250883 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k250883/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Mar 24, 2025
Decision date	Sep 18, 2025
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ULTRASONIC PROBE UM-G20-29R (UM-G20-29R)

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Olympus Surgical Technologies of the Americas</b>
Contact	Brenda Geary

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250883/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026