FDA 510(k) Premarket Notification

CLEARED

K250883 ULTRASONIC PROBE UM-3R (UM-3R)

Sep 18, 2025
178 days to decision

K250883 · 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	**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	Brenda Geary

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov