

K252237 EdgeFlow UW20Apr 17, 2026
274 days to decisionK252237 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k252237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jul 17, 2025
Decision date	Apr 17, 2026
Days to decision	274 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Edgcare, Inc.
Location	Seoul, KR
Contact	Beom Ki Cha
510(k) history	3 submissions · 3 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252237/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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