

K231677 EdgeFlow UH10Mar 6, 2024
271 days to decisionK231677 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k231677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jun 9, 2023
Decision date	Mar 6, 2024
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	KMC, Inc.
Contact	Milly .

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

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