FDA 510(k) Premarket Notification

K252337 EdgeFlow Gel Pad

CLEARED

Apr 24, 2026
270 days to decision

K252337 · Product code: **MUI** · Radiology
Source: https://www.510kdatabase.net/k252337/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Jul 28, 2025
Decision date	Apr 24, 2026
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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