

**K252337 EdgeFlow Gel Pad**Apr 24, 2026  
270 days to decisionK252337 · Product code: **MUI** · Radiology  
Source: <https://www.510kdatabase.net/k252337/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252337/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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