

K254277 Embrace Neonatal MRI SystemMar 13, 2026
73 days to decisionK254277 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k254277/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Dec 30, 2025
Decision date	Mar 13, 2026
Days to decision	73 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aspect Imaging, Ltd.
Location	Shoham, IL
Contact	Yaron Eshel
Website	https://www.aspectimaging.com
510(k) history	5 submissions · 5 cleared · 2013-2026

REGULATORY CONSULTANT

Consulting firm	MCRA
Contact	Alex Cadotte

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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