

K242258 MROpen Evo (03-2000-00)Nov 26, 2024
118 days to decisionK242258 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k242258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jul 31, 2024
Decision date	Nov 26, 2024
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MROpen Evo (03-4000-00)

APPLICANT

Company	Asg Superconductors S.P.A.
Location	Genova, IT
Contact	Leonardo Bertora
510(k) history	4 submissions · 4 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	THEMA S.r.l.
Contact	Silvia Tamarri

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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