

K242054 OptimMRI (v2)Aug 12, 2024
28 days to decisionK242054 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k242054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 15, 2024
Decision date	Aug 12, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rebrain, Sas
Location	Pessac, FR
Contact	Thomas Queuche
510(k) history	2 submissions · 2 cleared · 2023-2024

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