

K252362 GBrain MRIAug 22, 2025
24 days to decisionK252362 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k252362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 29, 2025
Decision date	Aug 22, 2025
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Galileo Cds, Inc.
Location	Austin, TX, US
Contact	Abhijeet Pradhan
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Innolitics, LLC
Contact	David Giese

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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