

K220815 BrainInsightJul 19, 2022
120 days to decisionK220815 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k220815/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 21, 2022
Decision date	Jul 19, 2022
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hyperfine, Inc.
Location	Guildford, CT, US
Contact	Christine Kupchick
510(k) history	13 submissions · 13 cleared · 2021-2025

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