

K202414 BrainInsightJan 7, 2021
136 days to decisionK202414 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k202414/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 24, 2020
Decision date	Jan 7, 2021
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hyperfine Research, Inc.
Location	Guildford, CT, US
Contact	Robert Fasciano
510(k) history	3 submissions · 3 cleared · 2020-2021

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