FDA 510(k) Premarket Notification

K223268 BrainInsight

CLEARED

Dec 16, 2022
53 days to decision

K223268 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k223268/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Oct 24, 2022
Decision date	Dec 16, 2022
Days to decision	53 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