

K233243 ClearPoint System (Software Version 2.2)Nov 27, 2023
60 days to decisionK233243 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k233243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 28, 2023
Decision date	Nov 27, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	ClearPoint Neuro, Inc.
Location	Irvine, CA, US
Contact	Brennan Sullivan
510(k) history	12 submissions · 11 cleared · 2021-2025

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