

K243657 ClearPoint System (Software Version 3.0)Jan 24, 2025
58 days to decisionK243657 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k243657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Nov 27, 2024
Decision date	Jan 24, 2025
Days to decision	58 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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