

K222519 ClearPoint SystemSep 16, 2022
28 days to decisionK222519 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k222519/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Aug 19, 2022
Decision date	Sep 16, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John J Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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