FDA 510(k) Premarket Notification

K222519 ClearPoint System

CLEARED

Sep 16, 2022
28 days to decision

K222519 · 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