FDA 510(k) Premarket Notification

K202575 ClearPoint Array System

CLEARED

Jan 22, 2021
140 days to decision

K202575 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k202575/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 4, 2020
Decision date	Jan 22, 2021
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John Smith

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