FDA 510(k) Premarket Notification

K214040 ClearPoint Array System (version 1.1)

CLEARED

Apr 12, 2022
110 days to decision

K214040 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k214040/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Dec 23, 2021
Decision date	Apr 12, 2022
Days to decision	110 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