FDA 510(k) Premarket Notification

K233141 SmartFrame OR

CLEARED

Jan 12, 2024
107 days to decision

K233141 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k233141/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 27, 2023
Decision date	Jan 12, 2024
Days to decision	107 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