FDA 510(k) Premarket Notification

K213645 ClearPoint Maestro Brain Model

CLEARED

Aug 8, 2022
263 days to decision

K213645 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k213645/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 18, 2021
Decision date	Aug 8, 2022
Days to decision	263 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 Lpp**
Contact	John J. Smith

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