FDA 510(k) Premarket Notification

K200079 ClearPoint System and Accessories

CLEARED

Feb 13, 2020
30 days to decision

K200079 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k200079/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jan 14, 2020
Decision date	Feb 13, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mri Interventions, Inc.**
Location	Irvine, CA, US
Contact	Pete Piferi
510(k) history	14 submissions · 14 cleared · 2011-2020

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