

K181195 ClearPoint SystemNov 2, 2018
182 days to decisionK181195 · Product code: **ORR** · Neurology
Source: <https://www.510kdatabase.net/k181195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument, Real-time Intraoperative Mri (ORR)
Date received	May 4, 2018
Decision date	Nov 2, 2018
Days to decision	182 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

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