

K142505 ClearPoint SystemOct 21, 2015
411 days to decisionK142505 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k142505/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 5, 2014
Decision date	Oct 21, 2015
Days to decision	411 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mri Interventions, Inc.
Location	Irvine, CA, US
Contact	E F Waddell
510(k) history	14 submissions · 14 cleared · 2011-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142505/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 18, 2026