

K191400 Voyager Trajectory Array Guide (V-TAG)Jun 21, 2019
28 days to decisionK191400 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k191400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	May 24, 2019
Decision date	Jun 21, 2019
Days to decision	28 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191400/> 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