

K191701 Arcus Head Fixation FrameNov 15, 2019
143 days to decisionK191701 · Product code: **HBL** · Neurology
Source: <https://www.510kdatabase.net/k191701/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holder, Head, Neurosurgical (skull Clamp) (HBL)
Date received	Jun 25, 2019
Decision date	Nov 15, 2019
Days to decision	143 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](https://accessdata.fda.gov)

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