FDA 510(k) Premarket Notification

K181731 MR Compatible Aspiration Kit

CLEARED

Nov 20, 2018
144 days to decision

K181731 · Product code: **GWG** · Neurology
Source: https://www.510kdatabase.net/k181731/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	Jun 29, 2018
Decision date	Nov 20, 2018
Days to decision	144 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