FDA 510(k) Premarket Notification

K203251 SOLOPASS System

CLEARED

Aug 27, 2021
296 days to decision

K203251 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k203251/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Nov 4, 2020
Decision date	Aug 27, 2021
Days to decision	296 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Intravent Medical Partners, LP**
Location	Hershey, PA, US
Contact	Adam Barner
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Msquared Associates, Inc.**
Contact	Connie Qiu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov