FDA 510(k) Premarket Notification

K251317 SOLOPASS 2.0 System

CLEARED

Sep 5, 2025
129 days to decision

K251317 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k251317/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Apr 29, 2025
Decision date	Sep 5, 2025
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Intravent Medical Partners**
Location	Blue Bell, PA, US
Contact	Adam Barner
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**ProPharma MedTech**
Contact	Connie Qiu

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k251317/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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