

K231897 NeuroAlign softwareOct 21, 2025
846 days to decisionK231897 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k231897/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jun 28, 2023
Decision date	Oct 21, 2025
Days to decision	846 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medivis, Inc.
Location	Brooklyn, NY, US
Contact	Amy Lynn
510(k) history	3 submissions · 3 cleared · 2019-2025

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