

K191422 Neural NavigatorApr 6, 2020
313 days to decisionK191422 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k191422/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	May 29, 2019
Decision date	Apr 6, 2020
Days to decision	313 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Soterix Medical, Inc.
Location	Woodbridge, NJ, US
Contact	Abhishek Datta
510(k) history	6 submissions · 6 cleared · 2017-2026

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