

K210700 NaviNetics D1 Stereotactic SystemJun 17, 2021
100 days to decisionK210700 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k210700/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Mar 9, 2021
Decision date	Jun 17, 2021
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Navinetics, Inc.
Location	Rochester, MN, US
Contact	Patrick Gora
510(k) history	2 submissions · 2 cleared · 2021-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210700/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026