

**K242575 Stereotaxic Guiding Surgical Devices, NaoTrac S**May 23, 2025  
267 days to decisionK242575 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k242575/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Aug 29, 2024
Decision date	May 23, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brain Navi Biotechnology Co., Ltd.</b>
Location	Hsinchu County, TW
Contact	I-Ju Lu
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Elite Biomedical Consulting, Inc.</b>
Contact	Feng-Yu Lee

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242575/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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