

**K241327 Navient Image Guide Navigation System (955-NC-NC),  
Cranial**Feb 5, 2025  
271 days to decisionK241327 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k241327/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	May 10, 2024
Decision date	Feb 5, 2025
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Claronav</b>
Location	Toronto, CA
Contact	Karen Wu
510(k) history	2 submissions · 2 cleared · 2025-2025

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241327/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026