

**K243053 Navient Image Guided Navigation System (ENT)  
(955-NC-NC)**Jun 20, 2025  
266 days to decisionK243053 · Product code: **PGW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k243053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Sep 27, 2024
Decision date	Jun 20, 2025
Days to decision	266 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/k243053/> 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