

**K183400 EnVisio Navigation System**Mar 22, 2019  
105 days to decisionK183400 · Product code: **NEU** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k183400/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Dec 7, 2018
Decision date	Mar 22, 2019
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Elucent Medical, Inc.</b>
Location	Eden Prairie, MN, US
Contact	Debra Kridner
510(k) history	3 submissions · 3 cleared · 2018-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183400/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026