

**K233784 ENSO (Model 2)**Feb 23, 2024  
88 days to decisionK233784 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k233784/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Nov 27, 2023
Decision date	Feb 23, 2024
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hinge Health, Inc.</b>
Location	San Francisco, CA, US
Contact	Brandon Casa de Calvo
510(k) history	2 submissions · 2 cleared · 2024-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ebg Advisors, Inc.</b>
Contact	Dawn Norman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233784/> 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