

**K254216 Enso for Migraine**Apr 16, 2026  
108 days to decisionK254216 · Product code: **PCC** · Neurology  
Source: <https://www.510kdatabase.net/k254216/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine (PCC)
Date received	Dec 29, 2025
Decision date	Apr 16, 2026
Days to decision	108 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	Roop Pandher
510(k) history	2 submissions · 2 cleared · 2024-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k254216/> 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 13, 2026