FDA 510(k) Premarket Notification

K233784 ENSO (Model 2)

CLEARED

Feb 23, 2024
88 days to decision

K233784 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k233784/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Ebg Advisors, Inc.**
Contact	Dawn Norman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov