

K243131 Triathlon ProNov 7, 2025
403 days to decisionK243131 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k243131/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 30, 2024
Decision date	Nov 7, 2025
Days to decision	403 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Biomedical
Location	Sunrise, FL, US
Contact	Jorge Millan
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243131/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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