FDA 510(k) Premarket Notification

K251958 VEINOPLUS Back

CLEARED

Dec 23, 2025
181 days to decision

K251958 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k251958/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Jun 25, 2025
Decision date	Dec 23, 2025
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dynapulse Medical**
Location	Minnetonka, MN, US
Contact	Steffen Magnell
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**MRC Global**
Contact	Danielle Besal

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