FDA 510(k) Premarket Notification

K251083 Compact II

CLEARED

Sep 12, 2025
156 days to decision

K251083 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k251083/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Apr 9, 2025
Decision date	Sep 12, 2025
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Enraf-Nonius, B.V.**
Location	Delft, NL
Contact	Lambert Luong
510(k) history	5 submissions · 5 cleared · 2003-2025

REGULATORY CONSULTANT

Consulting firm	**Qara Consulting, LLC**
Contact	Scott Blood

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