

K251083 Compact IISep 12, 2025
156 days to decisionK251083 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251083/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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