

K233485 M-WaveJan 26, 2024
91 days to decisionK233485 · Product code: **IPF** · Physical MedicineSource: <https://www.510kdatabase.net/k233485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Oct 27, 2023
Decision date	Jan 26, 2024
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Zynex Medical, Inc.
Location	Lone Tree, CO, US
Contact	Thomas Sandgaard
510(k) history	5 submissions · 5 cleared · 2011-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233485/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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