

K212832 TimeWaver FrequencyDec 14, 2021
98 days to decisionK212832 · Product code: **IPF** · Physical Medicine
Source: <https://www.510kdatabase.net/k212832/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Sep 7, 2021
Decision date	Dec 14, 2021
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Timewaver Production GmbH
Location	Kranzlin, DE
Contact	Babak Jafarian
510(k) history	2 submissions · 2 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	Herrington Consulting, LLC
Contact	Douglas Herrington

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212832/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026