FDA 510(k) Premarket Notification

K212832 TimeWaver Frequency

CLEARED

Dec 14, 2021
98 days to decision

K212832 · 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