FDA 510(k) Premarket Notification

K240347 PTG-05

CLEARED

Jul 21, 2024
167 days to decision

K240347 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k240347/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Feb 5, 2024
Decision date	Jul 21, 2024
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Medizinsysteme GmbH**
Location	Neu-Ulm, DE
Contact	Ute Killet
510(k) history	13 submissions · 13 cleared · 2016-2026

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