FDA 510(k) Premarket Notification

CLEARED

K221200 XBody Go USA, XBody Pro USA

Jan 31, 2023
280 days to decision

K221200 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k221200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Apr 26, 2022
Decision date	Jan 31, 2023
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xbody Hungary Kft.**
Location	Budapest, HU
Contact	Orsolya Balog
Website	http://xbodyworld.com/
510(k) history	3 submissions · 3 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy, Inc.**
Contact	Bhoomika Joyappa

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k221200/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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