FDA 510(k) Premarket Notification

CLEARED

K242926 XBody Go USA, XBody Pro USA

May 30, 2025
248 days to decision

K242926 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k242926/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Sep 24, 2024
Decision date	May 30, 2025
Days to decision	248 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