FDA 510(k) Premarket Notification

K230024 HI-EMT MAGSHAPE

CLEARED

Sep 6, 2023
245 days to decision

K230024 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k230024/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Jan 4, 2023
Decision date	Sep 6, 2023
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Sano Laser S&T Development Co.,Ltd**
Location	Beijing, CN
Contact	Hongbo Zhang
510(k) history	5 submissions · 5 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	**Microkn Medical Technology Service (Shanghai) Co., Ltd.**
Contact	Heather Wang

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