FDA 510(k) Premarket Notification

K232982 EMS Sculpt Machine

CLEARED

Nov 25, 2024
430 days to decision

K232982 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k232982/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Sep 22, 2023
Decision date	Nov 25, 2024
Days to decision	430 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shandong Huamei Technology Co., Ltd.**
Location	Weifang, CN
Contact	Dong Yugui
510(k) history	2 submissions · 2 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	**Beijing Believe-Med Technology Service Co., Ltd.**
Contact	Ray Wang

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