

K232982 EMS Sculpt MachineNov 25, 2024
430 days to decisionK232982 · Product code: **NGX** · Physical MedicineSource: <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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232982/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026