

K192264 HIVOX Spopad EMS SP-911, SP-921Nov 8, 2019
79 days to decisionK192264 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k192264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Aug 21, 2019
Decision date	Nov 8, 2019
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hivox Biotek, Inc.
Location	Taipei, TW
Contact	Marx Lee
510(k) history	17 submissions · 17 cleared · 2002-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192264/> 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 26, 2026