

K212948 Pain Therapy Device(Model: DH-P.T.S-I, DH-P.T.S-II, DH-P.T.S-IIA, DH-P.T.S-IIB, DH-CP-I)Nov 1, 2021
46 days to decisionK212948 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k212948/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Sep 16, 2021
Decision date	Nov 1, 2021
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Guangzhou Xinbo Electronic Co., Ltd.
Location	Guangzhou, CN
Contact	Sammy Li
510(k) history	12 submissions · 12 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie Lee

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/k212948/> 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 25, 2026