FDA 510(k) Premarket Notification

K231789 Pain Therapy Device (Model: P.T.S-VI, P.T.S-VII)

CLEARED

Mar 11, 2024
265 days to decision

K231789 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k231789/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Jun 20, 2023
Decision date	Mar 11, 2024
Days to decision	265 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