FDA 510(k) Premarket Notification

CLEARED

K202638 Pain Therapy Device

Jul 15, 2021
307 days to decision

K202638 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k202638/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Sep 11, 2020
Decision date	Jul 15, 2021
Days to decision	307 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