FDA 510(k) Premarket Notification

CLEARED

K202671 DR-HO's Back Pain Relief System Pro (Models BPRS-I and BPRS-II)

Nov 12, 2021
424 days to decision

K202671 · Product code: **NUH** · Physical Medicine
Source: https://www.510kdatabase.net/k202671/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 14, 2020
Decision date	Nov 12, 2021
Days to decision	424 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