FDA 510(k) Premarket Notification

CLEARED

K222201 Biological Feedback and Stimulation System

Oct 21, 2022
88 days to decision

K222201 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k222201/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Jul 25, 2022
Decision date	Oct 21, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medlander Medical Technology, Inc.**
Location	Nanjing, CN
Contact	Wang Wang
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Chonconn Medical Device Consulting Co., Ltd.**
Contact	Kevin Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov