FDA 510(k) Premarket Notification

CLEARED

K192733 RelieforMe TENS/EMS Device Model UPK-GE01

Dec 23, 2019
87 days to decision

K192733 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k192733/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Sep 27, 2019
Decision date	Dec 23, 2019
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Umeheal , Ltd.**
Location	Shenzhen, CN
Contact	Rui Lin
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting, LLC**
Contact	Randy Jiang

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