FDA 510(k) Premarket Notification

K233098 MYOTouch Muscle Stimulator

CLEARED

Aug 2, 2024
311 days to decision

K233098 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k233098/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Sep 26, 2023
Decision date	Aug 2, 2024
Days to decision	311 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sunmed, LLC**
Location	Daliang, Shunde, Foshan, CN
Contact	Robert Yamashita
510(k) history	2 submissions · 2 cleared · 2013-2024