CLEARED

K230500 Air Compression Therapy Recovery System (model: MF-AWI, MF-AWI.LED.A-801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601, MF-AWI.LED.A-601, MF-AWI.LED.B-601, MF-AWI.OLED.A-401, MF-AWI.LED.A-401, MF-AWI.LED.B-401)

Oct 26, 2023
244 days to decision

K230500 · Product code: **IRP** · Physical Medicine
Source: https://www.510kdatabase.net/k230500/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Feb 24, 2023
Decision date	Oct 26, 2023
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jiangsu Maxf Electric Appliance Co., Ltd.**
Location	Changzhou, CN
Contact	Zhang Jianfang
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Share Info (Guangzhou) Medical Consultant , Ltd.**
Contact	Cassie Lee

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