FDA 510(k) Premarket Notification

CLEARED

May 5, 2026
127 days to decision

K254200 Air Compression Leg Massager (LF-FT001, LF-FT002-1, LF-FT003, LF-FT003-1, LF-FT004-1, LF-FT005-1, LF-FT006-1, LF-FT007, LF-FT008, LF-FT009, LF-FT010, LF-FT011, LF-FT012, LF-FT013, LF-FT014, LF-FT015, LF-FT016, UM-01, UM-02, UM-03, UM-03-1, UM-04-1, UM-05-1, UM-06-1, UM-07, UM-08, UM-09, UM-10, UM-11, UM-12, UM-13, UM-14, UM-15, UM-16, AI-01, AI-02, AI-03, AI-04, AI-05, AI-06, AI01, AI02, AI03, AI-07, AI-08, AI-09, AI-10, AI-11, AI-12, AI-13, AI-14)

K254200 · Product code: **IRP** · Physical Medicine
Source: https://www.510kdatabase.net/k254200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Dec 29, 2025
Decision date	May 5, 2026
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wenzhou Lingfeng Electronic Technology Co., Ltd.**
Location	Ruian, CN
Contact	Xiaoqun Ye
510(k) history	2 submissions · 2 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Reanny Medical Devices Management Consulting Co.,Lt**
Contact	Reanny Wang

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