FDA 510(k) Premarket Notification

CLEARED

K213745 Air Compression Therapy Device, model: ST-502

Mar 31, 2022
122 days to decision

K213745 · Product code: **IRP** · Physical Medicine
Source: https://www.510kdatabase.net/k213745/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Nov 29, 2021
Decision date	Mar 31, 2022
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Future Electronic Co., Ltd.**
Location	Shenzhen, CN
Contact	Zhao Qihong
510(k) history	3 submissions · 3 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Qimmiq Medical Consulting Service Co., Ltd.**
Contact	You Yijie

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