FDA 510(k) Premarket Notification

CLEARED

K201982 Air compression therapy system FO-3001

Mar 25, 2021
251 days to decision

K201982 · Product code: **IRP** · Physical Medicine
Source: https://www.510kdatabase.net/k201982/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Jul 17, 2020
Decision date	Mar 25, 2021
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Air compression therapy system FO-3008

APPLICANT

Company	**Foshan Hongfeng Co., Ltd.**
Location	Foshan, CN
Contact	Cheng Dongfeng
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Shanghai Spica Management Consulting Co., Ltd.**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov