

K201935 Air Pressure Therapy SystemJun 22, 2021
344 days to decisionK201935 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k201935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Jul 13, 2020
Decision date	Jun 22, 2021
Days to decision	344 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xiamen Weiyou Intelligent Technology Co., Ltd.
Location	Xiamen, CN
Contact	Yong Sun
510(k) history	6 submissions · 6 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Shanghai Spica Management Consulting Co., Ltd.
Contact	Sam Lin

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201935/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026