

K243791 Air Pressure Therapy SystemJan 13, 2025
34 days to decisionK243791 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k243791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Dec 10, 2024
Decision date	Jan 13, 2025
Days to decision	34 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Ariel Xiang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243791/> 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 13, 2026