

K243320 Air Pressure Therapy System (VU-IPC04B)Nov 18, 2024
26 days to decisionK243320 · Product code: **IRP** · Physical MedicineSource: <https://www.510kdatabase.net/k243320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Oct 23, 2024
Decision date	Nov 18, 2024
Days to decision	26 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/k243320/> 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