

K240981 Air compression leg massagerAug 2, 2024
114 days to decisionK240981 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k240981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Apr 10, 2024
Decision date	Aug 2, 2024
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Huizhou Xinyi Technology Co., Ltd.
Location	Huizhou, CN
Contact	Eason Hu
510(k) history	2 submissions · 2 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Shenzhen Reanny Medical Devices Management Consulting Co.,Lt
Contact	Reanny Wang

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/k240981/> 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