

K222136 Cryo-Thermo Compression Device (FGK002)Mar 8, 2023
232 days to decisionK222136 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k222136/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Jul 19, 2022
Decision date	Mar 8, 2023
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Microport Rehabtech (Group) Co., Ltd.
Location	Suzhou, CN
Contact	Liang Hong
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Microport Sinica Co., Ltd.
Contact	Yunfang Sun

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/k222136/> 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 27, 2026