

K253150 Cryon-X Cold CompressionOct 24, 2025
29 days to decisionK253150 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k253150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Sep 25, 2025
Decision date	Oct 24, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jkh Health Co., Ltd.
Location	Shenzhen, CN
Contact	Jiang Pu
510(k) history	10 submissions · 10 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	Jkh USA, LLC
Contact	Bill Quanqin Dai

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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