

K223729 FLOWpressoDec 21, 2023
373 days to decisionK223729 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k223729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Dec 13, 2022
Decision date	Dec 21, 2023
Days to decision	373 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medella Health Limited
Location	Tauranga, NZ
Contact	Desiree De Spong
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Tilia Bridge
Contact	Samantha Nava

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/k223729/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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