

K242327 Empulse M90Dec 10, 2024
126 days to decision

K242327 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k242327/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Aug 6, 2024
Decision date	Dec 10, 2024
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Concourse Assistive Technology Pty, Ltd.
Location	Mount Kuring-Gai, AU
Contact	David Mackay
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Pierre Bounaud

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

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