

K220213 Empulse R90Mar 30, 2022
63 days to decision

K220213 · Product code: ITI · Physical Medicine

Source: <https://www.510kdatabase.net/k220213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	Jan 26, 2022
Decision date	Mar 30, 2022
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sunrise Medical (Us), LLC
Location	Fresno, CA, US
Contact	Devin McElroy
510(k) history	5 submissions · 5 cleared · 2014-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220213/> 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