FDA 510(k) Premarket Notification

CLEARED

K221654 medi pneumatic compression system (pcs)-genius (Model 652)

Jul 7, 2022
30 days to decision

K221654 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k221654/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Jun 7, 2022
Decision date	Jul 7, 2022
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medi USA, LP**
Location	Arlington Heights, IL, US
Contact	Moses Lipshaw
510(k) history	4 submissions · 4 cleared · 1994-2022

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k221654/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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