FDA 510(k) Premarket Notification

K211235 CIRCUL8 Luxe DVT Prevention Device

CLEARED

Sep 8, 2021
135 days to decision

K211235 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k211235/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Apr 26, 2021
Decision date	Sep 8, 2021
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ortho8, Inc.**
Location	Rocklin, CA, US
Contact	Taylor Nordeen
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	**Medtech Review, LLC**
Contact	John Beasley

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/k211235/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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