FDA 510(k) Premarket Notification

K220761 CIRCUL8 Connect DVT Prevention Device

CLEARED

Jun 3, 2022
80 days to decision

K220761 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k220761/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Mar 15, 2022
Decision date	Jun 3, 2022
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Ortho8, Inc.**
Location	Rocklin, CA, US
Contact	Jeff Culhane
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