FDA 510(k) Premarket Notification

K223193 AIROS 8P Sequential Compression Device

CLEARED

Dec 9, 2022
57 days to decision

K223193 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k223193/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Oct 13, 2022
Decision date	Dec 9, 2022
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Airos Medical, Inc.**
Location	Audubon, PA, US
Contact	Darren Behuniak
510(k) history	7 submissions · 7 cleared · 2018-2024