FDA 510(k) Premarket Notification

K223228 Dayspring

CLEARED

Jan 4, 2024
443 days to decision

K223228 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k223228/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Oct 18, 2022
Decision date	Jan 4, 2024
Days to decision	443 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Koya Medical, Inc.**
Location	Oakland, CA, US
Contact	Jarren Baldwin
510(k) history	3 submissions · 3 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**Biodesign Regulatory Services, LLC**
Contact	Alex Chang

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