

K223228 DayspringJan 4, 2024
443 days to decisionK223228 · 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](https://accessdata.fda.gov)

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