

K193288 Koya RippleJun 16, 2020
202 days to decisionK193288 · Product code: **JOW** · Cardiovascular
Source: <https://www.510kdatabase.net/k193288/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Nov 27, 2019
Decision date	Jun 16, 2020
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Koya, Inc.
Location	San Francisco, CA, US
Contact	Andy Doraiswamy
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Robert V. Packard

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

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