FDA 510(k) Premarket Notification

K193288 Koya Ripple

CLEARED

Jun 16, 2020
202 days to decision

K193288 · 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