FDA 510(k) Premarket Notification

K211253 PlasmaWave

CLEARED

May 26, 2021
30 days to decision

K211253 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k211253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Apr 26, 2021
Decision date	May 26, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Manamed, Inc.**
Location	Costa Mesa, CA, US
Contact	Trevor Theriot
510(k) history	7 submissions · 7 cleared · 2016-2023

REGULATORY CONSULTANT

Consulting firm	**Jkh USA, LLC**
Contact	Bill Quanqin Dai

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