

**K211253 PlasmaWave**May 26, 2021  
30 days to decisionK211253 · Product code: **JOW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k211253/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Jkh USA, LLC</b>
Contact	Bill Quanqin Dai

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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