

K251446 PlasmaFlow X Compression Sleeve Device (XPF0001)Sep 17, 2025
131 days to decisionK251446 · Product code: **JOW** · Cardiovascular
Source: <https://www.510kdatabase.net/k251446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	May 9, 2025
Decision date	Sep 17, 2025
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Manamed, LLC
Location	Denton, TX, US
Contact	Trevor Theriot
Website	https://manamed.com
510(k) history	1 submissions · 1 cleared · 2025-2025

Manamed, LLC designs and manufactures recovery and mobility solutions, including vascular therapy, lymphedema therapy, and cold therapy devices. The company operates with a manufacturing facility in Denton, Texas, and serves over 1,500 customers globally with a focus on post-operative rehabilitation and injury prevention. Manamed has received FDA 510(k) clearance from total submission. The company specializes in Cardiovascular devices, with its first and latest clearance both occurring in 2025. The cleared device, PlasmaFlow X Compression Sleeve Device, reflects the compa...