

K193020 VenaPro Vascular Therapy SystemDec 4, 2019
35 days to decisionK193020 · Product code: **JOW** · Cardiovascular
Source: <https://www.510kdatabase.net/k193020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Oct 30, 2019
Decision date	Dec 4, 2019
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innovamed Health, LLC
Location	Orange Park, FL, US
Contact	Luke Zeutzius
510(k) history	2 submissions · 2 cleared · 2014-2019

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193020/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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