FDA 510(k) Premarket Notification

K200285 VenaOne

CLEARED

Jul 2, 2020
148 days to decision

K200285 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k200285/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Feb 5, 2020
Decision date	Jul 2, 2020
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vena Group, LLC**
Location	San Antonio, TX, US
Contact	Kasey Vukson
510(k) history	1 submissions · 1 cleared · 2020-2020

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.net
Device record: https://www.510kdatabase.net/k200285/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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