

**K122609 VASCULAIRE COMPRESSION SYSTEM MODEL
FLS-0003**Dec 21, 2012
116 days to decisionK122609 · Product code: **JOW** · Cardiovascular
Source: <https://www.510kdatabase.net/k122609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Aug 27, 2012
Decision date	Dec 21, 2012
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary
Other names	VASCULAIRE SLEEVE (FOOT & CALF) MODEL FLS-0002; VASCULAIRE SLEEVE (CALF) F

APPLICANT

Company	Venous Health Systems, Inc.
Location	Sunnyvale, CA, US
Contact	RICH LAGUNA
510(k) history	3 submissions · 3 cleared · 2011-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122609/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 8, 2026