

K181651 Radial Medical Compression SystemOct 12, 2018
112 days to decisionK181651 · Product code: **JOW** · Cardiovascular
Source: <https://www.510kdatabase.net/k181651/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Jun 22, 2018
Decision date	Oct 12, 2018
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Radial Medical, Inc.
Location	Mountain View, CA, US
Contact	Eric Johnson
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	Mark Smutka
Contact	Mark Smutka

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/k181651/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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