FDA 510(k) Premarket Notification

K182150 Devon 52 Sequential Compression Device

CLEARED

Dec 18, 2018
132 days to decision

K182150 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k182150/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Aug 8, 2018
Decision date	Dec 18, 2018
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Devon Medical Products (Jiangsu), Ltd.**
Location	Nantong, CN
Contact	Neil Cheng
510(k) history	6 submissions · 6 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	**Devon MD, LLC**
Contact	Ruth Wu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov