FDA 510(k) Premarket Notification

K160180 Intermittent Pneumatic Compression system

CLEARED

Nov 3, 2016
281 days to decision

K160180 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k160180/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Jan 27, 2016
Decision date	Nov 3, 2016
Days to decision	281 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Daesung Maref Co., Ltd.**
Location	Buena Park, CA, US
Contact	Jae-wha Lee
510(k) history	14 submissions · 14 cleared · 2011-2023