FDA 510(k) Premarket Notification

K143438 Flowtron ACS900

CLEARED

Jun 23, 2015
203 days to decision

K143438 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k143438/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Dec 2, 2014
Decision date	Jun 23, 2015
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Getinge (Suzhou) Co., Ltd.**
Location	Suzhou, TW
Contact	Lenda Hou
510(k) history	2 submissions · 2 cleared · 2015-2018