

K152228 Hydroven 12, Hydroven 12 GarmentsApr 4, 2016
241 days to decisionK152228 · Product code: **JOW** · Cardiovascular
Source: <https://www.510kdatabase.net/k152228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Aug 7, 2015
Decision date	Apr 4, 2016
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Huntleigh Healthcare , Ltd.
Location	Cardiff, GB
Contact	GREG BAILY
Website	http://www.huntleigh-diagnostics.com/diagnostics/uk/
510(k) history	8 submissions · 8 cleared · 2006-2025

Huntleigh Healthcare, Ltd. is a leading global provider of innovative medical devices for vascular assessment and treatment, fetal monitoring, and patient monitoring. A proud member of the Arjo family, the company operates with a manufacturing facility in Cardiff, United Kingdom, and serves healthcare professionals across more than 100 countries with over 40 years of clinical expertise. The company has received FDA 510(k) clearances from total submissions since 2006, with no denied submissions. Huntleigh's cleared devices span Obstetrics & Gynecology, Cardiovascular, and ...
