

**K183574 SRX Handheld Doppler, DMX Handheld Doppler,
Obstetric Probes, Vascular Probes**Sep 6, 2019
259 days to decisionK183574 · Product code: **DPW** · Cardiovascular
Source: <https://www.510kdatabase.net/k183574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Dec 21, 2018
Decision date	Sep 6, 2019
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Huntleigh Healthcare , Ltd.
Location	Cardiff, GB
Contact	Steve Monks
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 ...

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