

K142607 AngioVac CircuitDec 11, 2014
87 days to decisionK142607 · Product code: **DWE** · Cardiovascular
Source: <https://www.510kdatabase.net/k142607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubing, Pump, Cardiopulmonary Bypass (DWE)
Date received	Sep 15, 2014
Decision date	Dec 11, 2014
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Angiodynamics
Location	Marlborough, MA, US
Contact	Gary Barrett
Website	http://www.angiodynamics.com/
510(k) history	3 submissions · 3 cleared · 2014-2026

AngioDynamics is a global leader in vascular and oncology medical technologies, with a manufacturing facility in Marlborough, US. The company develops advanced devices addressing blood flow restoration, cancer treatment, and vascular interventions. AngioDynamics has received FDA 510(k) clearances from total submissions since its first clearance in 2014. The company's cleared devices span Gastroenterology & Urology, Cardiovascular, and General & Plastic Surgery categories. The latest clearance in 2026 confirms continued regulatory activity and product innovation. The compa...
