FDA 510(k) Premarket Notification

K212386 AngioVac F18 85

CLEARED

Sep 30, 2021
59 days to decision

K212386 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k212386/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Aug 2, 2021
Decision date	Sep 30, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**AngioDynamics, Inc.**
Location	Glens Falls, NY, US
Contact	Kasey E. Newcomb
Website	http://www.angiodynamics.com/
510(k) history	87 submissions · 82 cleared · 1995-2025

AngioDynamics, Inc. is a global leader in vascular and oncology medical technologies, with a manufacturing facility in Glens Falls, US. The company develops advanced devices addressing blood flow restoration, cancer therapies, vascular access, and varicose vein treatment. AngioDynamics has received FDA 510(k) clearances from total submissions since its first clearance in 1995. The company specializes in cardiovascular devices, with recent cleared products including mechanical aspiration systems, infusion systems, and angiographic catheters. The latest FDA 510(k) clearance...

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Device record: https://www.510kdatabase.net/k212386/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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