FDA 510(k) Premarket Notification

K953825 ANGIOFLUSH II FLUID MANAGEMENT SYSTEM

CLEARED

Feb 26, 1996
195 days to decision

K953825 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k953825/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Aug 15, 1995
Decision date	Feb 26, 1996
Days to decision	195 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**AngioDynamics, Inc.**
Location	Glens Falls, NY, US
Contact	BRIAN KUNST
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...