FDA 510(k) Premarket Notification

K964033 3F ANGIOPTIC ANGIOGRAPHIC CATHETER

CLEARED

May 6, 1997
210 days to decision

K964033 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k964033/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Oct 8, 1996
Decision date	May 6, 1997
Days to decision	210 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...