

K971314 DCAT EMBOLECTOMY CATHETER SYSTEMMar 17, 1998
342 days to decisionK971314 · Product code: **DXE** · Cardiovascular
Source: <https://www.510kdatabase.net/k971314/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	Apr 9, 1997
Decision date	Mar 17, 1998
Days to decision	342 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...
