

K033443 SPEEDLYSER INFUSION CATHETER KITNov 19, 2003
21 days to decisionK033443 · Product code: **QEY** · Cardiovascular
Source: <https://www.510kdatabase.net/k033443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - KD
Submission type	Special
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Oct 29, 2003
Decision date	Nov 19, 2003
Days to decision	21 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	AngioDynamics, Inc.
Location	Glens Falls, NY, US
Contact	TERI JUCKETT
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...
