

K202347 UNIFUSE Infusion System with Cooper WireSep 15, 2020
28 days to decisionK202347 · Product code: **QEY** · Cardiovascular
Source: <https://www.510kdatabase.net/k202347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Aug 18, 2020
Decision date	Sep 15, 2020
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	AngioDynamics, Inc.
Location	Glens Falls, NY, US
Contact	Brandon M. Brackett
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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