FDA 510(k) Premarket Notification

CLEARED

K192864 UNI*FUSE Infusion System with Cooper Wire

Jun 1, 2020
238 days to decision

K192864 · Product code: **QEY** · Cardiovascular
Source: https://www.510kdatabase.net/k192864/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Oct 7, 2019
Decision date	Jun 1, 2020
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	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...