

**K170258 SpeedLyser Infusion Catheter Kit**Feb 21, 2017  
25 days to decisionK170258 · Product code: **QEY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k170258/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mechanical Thrombolysis Catheter (QEY)
Date received	Jan 27, 2017
Decision date	Feb 21, 2017
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>AngioDynamics, Inc.</b>
Location	Glens Falls, NY, US
Contact	Teri Juckett
Website	<a href="http://www.angiodynamics.com/">http://www.angiodynamics.com/</a>
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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