

**K170775 Mini Stick ENVI Non-Vascular Introducer Kit**Jul 19, 2017  
127 days to decisionK170775 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k170775/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 14, 2017
Decision date	Jul 19, 2017
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>AngioDynamics, Inc.</b>
Location	Glens Falls, NY, US
Contact	Hans Kjolhede
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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