

**K181044 400um Perforator and Accessory Vein Ablation Kit**Jul 5, 2018  
77 days to decisionK181044 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k181044/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 19, 2018
Decision date	Jul 5, 2018
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>AngioDynamics, Inc.</b>
Location	Glens Falls, NY, US
Contact	Deepa R. Godhiya
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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