

**K100199 ANGIODYNAMICS, INC., PERCUTANEOUS
INTRODUCER AND VENACUREEVLVLT PROCEDURE KIT**Nov 26, 2010
308 days to decisionK100199 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k100199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 22, 2010
Decision date	Nov 26, 2010
Days to decision	308 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	AngioDynamics, Inc.
Location	Glens Falls, NY, US
Contact	TERI JUCKETT
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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