

K171921 VenaCure EVLT NeverTouch Procedure KitAug 24, 2017
58 days to decisionK171921 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k171921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 27, 2017
Decision date	Aug 24, 2017
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	AngioDynamics, Inc.
Location	Glens Falls, NY, US
Contact	Hans Kjolhede
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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