

K231945 VenaCure EVLT NeverTouch Procedure KitsJul 20, 2023
20 days to decisionK231945 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k231945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 30, 2023
Decision date	Jul 20, 2023
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VenaCure EVLT NeverTouch Direct Procedure Kits

APPLICANT

Company	AngioDynamics, Inc.
Location	Glens Falls, NY, US
Contact	Laura Dwyer
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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