FDA 510(k) Premarket Notification

CLEARED

K133561 VENACURE EVLT NEVERTOUCH PROCEDURE KIT, VENACURE EVLT TRE' SHEATH

Dec 19, 2013
29 days to decision

K133561 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k133561/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 20, 2013
Decision date	Dec 19, 2013
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**AngioDynamics, Inc.**
Location	Glens Falls, NY, US
Contact	Lorraine M Hanley
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...