

K081472 SMARTPORT CT VORTEXSep 23, 2008
119 days to decisionK081472 · Product code: LJT · General Hospital
Source: <https://www.510kdatabase.net/k081472/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT)
Date received	May 27, 2008
Decision date	Sep 23, 2008
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary
Other names	LP TITANIUM, SINGLE PLASTIC, SINGLE TITANIUM, TRIUMPH LOW PROFILE TITANIUM PORTS

APPLICANT

Company	AngioDynamics, Inc.
Location	Glens Falls, NY, US
Contact	BRIAN KUNST
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...
