

K190559 SmartPort+ Implantable Ports, SmartPort Plastic Implantable Ports

May 22, 2020
444 days to decisionK190559 · Product code: LJT · General Hospital
Source: <https://www.510kdatabase.net/k190559/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT)
Date received	Mar 5, 2019
Decision date	May 22, 2020
Days to decision	444 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	AngioDynamics, Inc.
Location	Glens Falls, NY, US
Contact	Vidyalakshmi Jayaraman
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...