FDA 510(k) Premarket Notification

K991793 ANGIODYNAMICS BALLOON EXPANDABLE BILIARY STENT SYSTEM

CLEARED

Jun 25, 1999
30 days to decision

K991793 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k991793/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	May 26, 1999
Decision date	Jun 25, 1999
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**AngioDynamics, Inc.**
Location	Glens Falls, NY, US
Contact	TERI JUCKETT
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...