

K982346 ANGIODYNAMICS ANGIOSTENT BILIARY STENT SYSTEMJan 29, 1999
207 days to decisionK982346 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k982346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 6, 1998
Decision date	Jan 29, 1999
Days to decision	207 days
Third-party review	No
Summary / Statement	Statement

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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k982346/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026