

K141969 FIRSTSTIC N INTRODUCERDec 19, 2014
151 days to decisionK141969 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k141969/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 21, 2014
Decision date	Dec 19, 2014
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Argon Medical Devices, Inc.
Location	Athens, TX, US
Contact	SUZANNE CHEANG
Website	https://www.argonmedical.com
510(k) history	20 submissions · 20 cleared · 2007-2026

Argon Medical Devices, Inc. manufactures specialty interventional medical devices. The company is based in Athens, US. Argon has received FDA 510(k) clearances from total submissions since 2007. The company specializes in Cardiovascular devices, which represent the dominant focus of its regulatory portfolio. The latest clearance was in 2026, reflecting continued active development and market engagement. Argon's cleared device portfolio includes thrombectomy systems, vascular access devices, biopsy instruments, and retrieval kits. The company also offers custom product sol...
