

K233432 10F Sheath and Dilator SetDec 8, 2023
57 days to decisionK233432 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k233432/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Oct 12, 2023
Decision date	Dec 8, 2023
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Argon Medical Devices, Inc.
Location	Athens, TX, US
Contact	Ana Jimenez-Hughes
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...

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Device record: <https://www.510kdatabase.net/k233432/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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