

**K201489 Traveler38 0.038 Stylet Portal Vein Access Set,
Traveler21 21ga Needle Portal Vein Access Set, Traveler16 16ga
Needle Portal Vein Access set**Dec 22, 2020
201 days to decisionK201489 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k201489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 4, 2020
Decision date	Dec 22, 2020
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Argon Medical Devices, Inc.
Location	Athens, TX, US
Contact	Amy Clendening-Wheeler
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...