

K202141 Scorpion Stylet Portal Vein Access Set, Scorpion Needle Portal Vein Access Set

Jan 15, 2021
168 days to decision

K202141 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k202141/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Jul 31, 2020 |
| Decision date | Jan 15, 2021 |
| Days to decision | 168 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 | 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...