FDA 510(k) Premarket Notification

CLEARED

K232679 Cleaner™ Pro Thrombectomy System

Jan 19, 2024
140 days to decision

K232679 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k232679/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Sep 1, 2023
Decision date	Jan 19, 2024
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Cleaner™ Pro Aspiration Catheter with Handpiece; Cleaner™ Pro Aspiration Canister

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...