FDA 510(k) Premarket Notification

K200268 Halo™ Single-Loop Snare Kit

CLEARED

Jun 3, 2020
121 days to decision

K200268 · Product code: **MMX** · Cardiovascular
Source: https://www.510kdatabase.net/k200268/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Percutaneous Retrieval (MMX)
Date received	Feb 3, 2020
Decision date	Jun 3, 2020
Days to decision	121 days
Third-party review	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...