FDA 510(k) Premarket Notification

K241145 TLAB® Transvenous Liver Biopsy System (TF-18C)

CLEARED

Aug 1, 2024
98 days to decision

K241145 · Product code: **DYB** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k241145/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 25, 2024
Decision date	Aug 1, 2024
Days to decision	98 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	Jacquelyn Huyghue
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...