FDA 510(k) Premarket Notification

CLEARED

K230631 Kodiak™ Dual Port Coaxial Introducer Kit

May 22, 2023
76 days to decision

K230631 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k230631/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 7, 2023
Decision date	May 22, 2023
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Argon Medical Devices**
Location	Athens, TX, US
Contact	Pratusha Kudumula
510(k) history	5 submissions · 5 cleared · 2021-2023