

K230631 Kodiak™ Dual Port Coaxial Introducer KitMay 22, 2023
76 days to decisionK230631 · Product code: **DYB** · CardiovascularSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230631/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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