FDA 510(k) Premarket Notification

K243061 SonoStik Guide Wire Introducer

CLEARED

Nov 4, 2024
38 days to decision

K243061 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k243061/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Sep 27, 2024
Decision date	Nov 4, 2024
Days to decision	38 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sonostik, LLC**
Location	N Potomac, MD, US
Contact	Gary Wakeford
510(k) history	2 submissions · 2 cleared · 2015-2024

REGULATORY CONSULTANT

Consulting firm	**Keystone Regulatory Services, LLC**
Contact	Robert McLain

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov