

**K243061 SonoStik Guide Wire Introducer**Nov 4, 2024  
38 days to decisionK243061 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k243061/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Keystone Regulatory Services, LLC</b>
Contact	Robert McLain

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

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