

**K251673 X9 Ultrasound System**Oct 17, 2025  
140 days to decisionK251673 · Product code: **SGH** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k251673/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ultrasound Imaging For Vascular Access For Hemodialysis (SGH)
Date received	May 30, 2025
Decision date	Oct 17, 2025
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>X9, Inc.</b>
Location	Wallingford, CT, US
Contact	Melissa Viotti
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251673/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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