

**K180461 Navi e/Navi s/Navi X Diagnostic Ultrasound System**May 9, 2018  
78 days to decisionK180461 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k180461/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 20, 2018
Decision date	May 9, 2018
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Wisonic Medical Technology Co. , Ltd.</b>
Location	Shenzhen, CN
Contact	Jiang Xiaosan
510(k) history	7 submissions · 7 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180461/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026