

**K192254 InnoSight Diagnostic Ultrasound System**Sep 18, 2019  
29 days to decisionK192254 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k192254/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 20, 2019
Decision date	Sep 18, 2019
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Qisda Corporation</b>
Location	Dublin, CA, US
Contact	Johnson Sheu
510(k) history	4 submissions · 4 cleared · 2014-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192254/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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