

**K190228 Transcranial Doppler Ultrasound System**Jun 13, 2019  
128 days to decisionK190228 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k190228/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 5, 2019
Decision date	Jun 13, 2019
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Delica Medical Equipment Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Yolanda Lan
510(k) history	3 submissions · 3 cleared · 2018-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190228/> 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 27, 2026