

**K182165 Color Doppler Ultrasound System**Dec 20, 2018  
132 days to decisionK182165 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k182165/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 10, 2018
Decision date	Dec 20, 2018
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Model: mEye1 and mEye2

**APPLICANT**

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Company	<b>Shenzhen Well.D Medical Electronics Co., Ltd.</b>
Location	Shanghai, CN
Contact	Ning Bai
510(k) history	2 submissions · 2 cleared · 2010-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

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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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182165/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 19, 2026