

K213009 Transcranial Doppler Ultrasound SystemJul 8, 2022
291 days to decisionK213009 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k213009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 20, 2021
Decision date	Jul 8, 2022
Days to decision	291 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Delica Medical Equipment Co., Ltd.
Location	Shenzhen, CN
Contact	Zhenhua Xiao
510(k) history	3 submissions · 3 cleared · 2018-2022

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
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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