

K183041 Full Digital Colour Doppler Ultrasonic Diagnostic SystemJul 10, 2019
251 days to decisionK183041 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k183041/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 1, 2018
Decision date	Jul 10, 2019
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wuhan Zoncare Bio-medical Electronics Co., Ltd.
Location	Wuhan, CN
Contact	Chenglin Tian
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Shenzhen Hlongmed Biotech Co., Ltd.
Contact	Long Yang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183041/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026