

K230066 Carnation series Diagnostic Ultrasound SystemSep 15, 2023
249 days to decisionK230066 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k230066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 9, 2023
Decision date	Sep 15, 2023
Days to decision	249 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Wisonic Medical Technology Co. , Ltd.
Location	Shenzhen, CN
Contact	Jiang Xiaosan
510(k) history	7 submissions · 7 cleared · 2018-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230066/> 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 May 26, 2026