

**K253716 uSONIQUE Genesis, uSONIQUE Genesis Pro,
uSONIQUE Genesis Elite, uSONIQUE Genesis Super,
uSONIQUE Pulse, uSONIQUE Pulse Pro, uSONIQUE Pulse Elite,
uSONIQUE Pulse Super, uSONIQUE Venus, uSONIQUE Venus
Pro, uSONIQUE Venus Elite, uSONIQUE Venus Super**

May 15, 2026
172 days to decision

K253716 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k253716/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 24, 2025
Decision date	May 15, 2026
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wuhan United Imaging Healthcare Co.,Ltd
Location	Wuhan, CN
Contact	Xin GAO
510(k) history	2 submissions · 2 cleared · 2026-2026
