

K253720 uSONIQUE Nova, uSONIQUE Nova Elite, uSONIQUE Vita, uSONIQUE Vita Elite, uSONIQUE Grace, uSONIQUE Grace EliteMay 21, 2026
178 days to decisionK253720 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k253720/>**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 21, 2026
Days to decision	178 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

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