

K254028 Digital Color Doppler Ultrasound System (Autra RS, Autra 90, Autra Senior, Autra CV, e-Autra, Autra 75, Autra 85W, Autra 65, Autra 55, Autra 65i, Autra 90 Elite, Autra 85 Elite, Autra 80 Elite, Autra 75 Elite, Autra 85 CV, Autra 80W, Autra 65 Elite, Autra 55 Elite, Autra 55i, Autra 90 CV, Autra 85, Autra 80, Autra 80 CV, Autra 75 Pro, Autra 75W, Autra 70 Elite, Autra 70, Autra T)

May 15, 2026
150 days to decision

K254028 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k254028/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 16, 2025
Decision date	May 15, 2026
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sonoscape Medical Corp.
Location	Shenzhen, CN
Contact	Toki Wu
510(k) history	25 submissions · 25 cleared · 2015-2026
