

K252498 Digital Color Doppler Ultrasound System (X11 Exp/X11 Elite/X11 Pro/X11 Plus/X11 Super/X11 Senior/X11/E11/E11 Pro/E11 Plus/E11 Elite/X11T/X11U/X11R/X11i/X11s/E11T/E11i/E11s/XR1/XR2/XR3/ER1/ER2/ER3/X10 Exp/X10 Elite/X10 Pro/X10 Plus/X10 Super/X10 Senior/X10/X10T/X10U/ X10R/X10i/X10s/E10/E10 Pro/E10 Plus/E10T/E10i/E10s/SU11A EXP/SU11A PRO/SU11A AD/ SU11A CU/SU11B EXP/SU11B PRO/SU11B AD/SU11B CU/SU11C EXP/SU11C PRO/SU11C AD/ SU11C CU)

Dec 5, 2025
119 days to decision

K252498 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k252498/>

SUBMISSION DETAILS

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Aug 8, 2025 |
| Decision date | Dec 5, 2025 |
| Days to decision | 119 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 | 24 submissions · 24 cleared · 2015-2025 |
