

K220169 SonoMe Wireless Probe Type Ultrasound Scanner (Model: 5C, 5CB, H5C, 10L, 14L, 10LB, H10L, H5C10L) and SonoFinder Wireless Probe Type Ultrasound Scanner (Model: SF14L25)Oct 11, 2022
264 days to decisionK220169 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k220169/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 20, 2022
Decision date	Oct 11, 2022
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bionet Co., Ltd.
Location	Wonju, Kwangwon-Do, KR
Contact	ChuelWon Lee
510(k) history	11 submissions · 11 cleared · 2005-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220169/> 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