

K212160 SimpleSENSE PlatformSep 22, 2021
72 days to decisionK212160 · Product code: **DXH** · CardiovascularSource: <https://www.510kdatabase.net/k212160/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Jul 12, 2021
Decision date	Sep 22, 2021
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nanowear, Inc.
Location	Brooklyn, NY, US
Contact	Venkatesh Varadan
510(k) history	4 submissions · 4 cleared · 2016-2023

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