

K221530 ANNE PediatricNov 22, 2022
180 days to decisionK221530 · Product code: **DRG** · CardiovascularSource: <https://www.510kdatabase.net/k221530/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	May 26, 2022
Decision date	Nov 22, 2022
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sibel, Inc.
Location	Niles, IL, US
Contact	Sarah Coughlin
510(k) history	3 submissions · 3 cleared · 2021-2022

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