FDA 510(k) Premarket Notification

K211305 ANNE One

CLEARED

Sep 14, 2021
138 days to decision

K211305 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k211305/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Apr 29, 2021
Decision date	Sep 14, 2021
Days to decision	138 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov