FDA 510(k) Premarket Notification

CLEARED

K202868 LifeSignals Multi-Parameter Remote Monitoring Platform

Jul 21, 2021
296 days to decision

K202868 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k202868/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Sep 28, 2020
Decision date	Jul 21, 2021
Days to decision	296 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lifesignals, Inc.**
Location	Fremont, CA, US
Contact	Saravanan Balasubramanian
510(k) history	3 submissions · 3 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	**MethodSense, Inc.**
Contact	Rita King

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