FDA 510(k) Premarket Notification

CLEARED

K191331 Life Sensor Cardiac Monitor

Jun 12, 2019
27 days to decision

K191331 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k191331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	May 16, 2019
Decision date	Jun 12, 2019
Days to decision	27 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Braveheart Wireless, Inc.**
Location	Nashua, NH, US
Contact	Balaji Sudabattula
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Accelerated Device Approval Services**
Contact	Rafael Aguila

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