FDA 510(k) Premarket Notification

K191620 Vitls Platform

CLEARED

Jun 1, 2020
349 days to decision

K191620 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k191620/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Jun 18, 2019
Decision date	Jun 1, 2020
Days to decision	349 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vitls, Inc.**
Location	Houston, TX, US
Contact	Werner Vorster
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**O'Connell Regulatory Consultants, Inc.**
Contact	Maureen O'Connell

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