FDA 510(k) Premarket Notification

K222398 Care Team Portal

CLEARED

Feb 6, 2023
182 days to decision

K222398 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k222398/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Aug 8, 2022
Decision date	Feb 6, 2023
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vivify Health, Inc.**
Location	Plano, TX, US
Contact	Tracey Fox
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Jodi Scott

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