FDA 510(k) Premarket Notification

CLEARED

K192952 Spire Health Remote Patient Monitoring System

Jun 5, 2020
228 days to decision

K192952 · Product code: **MSX** · Cardiovascular
Source: https://www.510kdatabase.net/k192952/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Oct 21, 2019
Decision date	Jun 5, 2020
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spire, Inc. D/B/A Spire Health**
Location	San Francisco, CA, US
Contact	Joanne Hollenbach
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Enzyme Corporation**
Contact	Jared Seehafer

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