

K211365 Alio Medical Remote Monitoring SystemMar 24, 2022
324 days to decisionK211365 · Product code: **DRG** · Cardiovascular
Source: <https://www.510kdatabase.net/k211365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	May 4, 2021
Decision date	Mar 24, 2022
Days to decision	324 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Graftworx, Inc. Db a Alio
Location	San Francisco, CA, US
Contact	David Kuraguntla
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Allison Komiyama

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

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