FDA 510(k) Premarket Notification

CLEARED

K222712 Fogg System Patient Monitoring Cables

Nov 22, 2023
440 days to decision

K222712 · Product code: **DSA** · Cardiovascular
Source: https://www.510kdatabase.net/k222712/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cable, Transducer And Electrode, Patient, (including Connector) (DSA)
Date received	Sep 8, 2022
Decision date	Nov 22, 2023
Days to decision	440 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fogg System Company, Inc.**
Location	Aurora, CO, US
Contact	Ken Neef
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Novare Medical Consulting, LLC**
Contact	Jared Walkenhorst

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