FDA 510(k) Premarket Notification

K211941 9Line

CLEARED

Jan 27, 2022
218 days to decision

K211941 · Product code: **DSA** · Cardiovascular
Source: https://www.510kdatabase.net/k211941/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cable, Transducer And Electrode, Patient, (including Connector) (DSA)
Date received	Jun 23, 2021
Decision date	Jan 27, 2022
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Energetic Designs, Inc.**
Location	Broomfield, CO, US
Contact	Kathy Fortin
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**FDA 510k Consultants, LLC**
Contact	John F. Gillespy

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