FDA 510(k) Premarket Notification

CLEARED

K201921 Spacelabs Lifescreen PRO Analyzer

Mar 26, 2021
259 days to decision

K201921 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k201921/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jul 10, 2020
Decision date	Mar 26, 2021
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spacelabs Healthcare, Ltd.**
Location	Nederland, CO, US
Contact	Roger Moldon
510(k) history	9 submissions · 9 cleared · 2011-2022

REGULATORY CONSULTANT

Consulting firm	**Speed TO Market, Inc.**
Contact	Thomas Kroenke

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k201921/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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