FDA 510(k) Premarket Notification

CLEARED

K231282 LifeOutcomes C-Quest™ Blood Culture Sampling Device

Jan 26, 2024
268 days to decision

K231282 · Product code: **JKA** · General Hospital
Source: https://www.510kdatabase.net/k231282/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	May 3, 2023
Decision date	Jan 26, 2024
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lifeoutcomes, LLC**
Location	Englewood, CO, US
Contact	Robert J. McKinnon
510(k) history	1 submissions · 1 cleared · 2024-2024

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/k231282/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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