CLEARED

Dec 29, 2021
518 days to decision

K202101 GEM Hemochron 100 System, GEM Hemochron 100 Activated Clotting Time Plus Test (ACT+), GEM Hemochron 100 Low Range Activated Clotting Time Test (ACT-LR), directCHECK ACT+ Whole Blood Control, Level 1 and Level 2, directCHECK ACT-LR Whole Blood Control, Level 1 and Level 2

K202101 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k202101/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jul 29, 2020
Decision date	Dec 29, 2021
Days to decision	518 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Accriva Diagnostics, Inc.**
Location	San Diego, CA, US
Contact	Brian James
510(k) history	3 submissions · 3 cleared · 2019-2023