FDA 510(k) Premarket Notification

K222635 Premier Resolution System

CLEARED

Aug 4, 2023
338 days to decision

K222635 · Product code: **GKA** · Hematology
Source: https://www.510kdatabase.net/k222635/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Hemoglobin Quantitation (GKA)
Date received	Aug 31, 2022
Decision date	Aug 4, 2023
Days to decision	338 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Trinity Biotech (Primus Corporation, Dba Trinity Biotech)**
Location	Kansas City, MO, US
Contact	Kaitlyn Eastman
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k222635/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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