FDA 510(k) Premarket Notification

K192931 V8 Nexus Hemoglobin Ultrascreen, V8 AFSA2 Hemo Control

CLEARED

Apr 19, 2022
915 days to decision

K192931 · Product code: **GKA** · Hematology
Source: https://www.510kdatabase.net/k192931/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Hemoglobin Quantitation (GKA)
Date received	Oct 17, 2019
Decision date	Apr 19, 2022
Days to decision	915 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Helena Laboratories, Corp.**
Location	Beaumont, TX, US
Contact	Justin Padia
510(k) history	2 submissions · 2 cleared · 2022-2022