

K192931 V8 Nexus Hemoglobin Ultrascreen, V8 AFSA2 Hemo ControlApr 19, 2022
915 days to decisionK192931 · 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

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