

K181751 HemoCue Hb 801 SystemFeb 1, 2019
214 days to decisionK181751 · Product code: **GKR** · Hematology
Source: <https://www.510kdatabase.net/k181751/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Jul 2, 2018
Decision date	Feb 1, 2019
Days to decision	214 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hemocue AB
Location	Lake Forest, CA, US
Contact	Maria Fagerberg
510(k) history	6 submissions · 6 cleared · 2006-2020

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