

K171655 cobas m 511 integrated hematology analyzerMar 2, 2018
270 days to decisionK171655 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k171655/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jun 5, 2017
Decision date	Mar 2, 2018
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Hematology, Inc.
Location	Westborough, MA, US
Contact	Dan Bracco
510(k) history	1 submissions · 1 cleared · 2018-2018

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