

K172173 DiaSpect Tm, DiaSpect Tm CuvettesApr 6, 2018
261 days to decisionK172173 · Product code: **GKR** · Hematology
Source: <https://www.510kdatabase.net/k172173/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Jul 19, 2017
Decision date	Apr 6, 2018
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ekf Diagnostic GmbH
Location	Egale, WI, US
Contact	Mick Fenton
510(k) history	5 submissions · 5 cleared · 2003-2020

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