

K180509 Quo-Test A1c SystemFeb 16, 2019
354 days to decisionK180509 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k180509/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Feb 27, 2018
Decision date	Feb 16, 2019
Days to decision	354 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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