FDA 510(k) Premarket Notification

K200909 Hemo Control (optional Add Pack Hemo Control DM)

CLEARED

Jun 12, 2020
67 days to decision

K200909 · Product code: **GKR** · Hematology
Source: https://www.510kdatabase.net/k200909/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Apr 6, 2020
Decision date	Jun 12, 2020
Days to decision	67 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ekf Diagnostic GmbH**
Location	Egale, WI, US
Contact	Andrew J. Rutter
510(k) history	5 submissions · 5 cleared · 2003-2020