FDA 510(k) Premarket Notification

K812127 KING DIAGNOSTICS HEMOGLOBIN TEST

CLEARED

Aug 25, 1981
29 days to decision

K812127 · Product code: **GKR** · Hematology
Source: https://www.510kdatabase.net/k812127/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Jul 27, 1981
Decision date	Aug 25, 1981
Days to decision	29 days
Third-party review	No

APPLICANT

Company	**King Diagnostics, Inc.**
Location	Walker, MI, US
510(k) history	41 submissions · 41 cleared · 1981-1993