FDA 510(k) Premarket Notification

K041234 HEMOCUE HEMOGLOBIN 201DM ANALYZING SYSTEM

CLEARED

Jun 10, 2004
31 days to decision

K041234 · Product code: **GKR** · Hematology
Source: https://www.510kdatabase.net/k041234/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Hemoglobin, Automated (GKR)
Date received	May 10, 2004
Decision date	Jun 10, 2004
Days to decision	31 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Hemocue, Inc.**
Location	Potomac, MD, US
Contact	R.J. SLOMOFF
510(k) history	9 submissions · 9 cleared · 1991-2004