

K831618 HEMOGLOBIN REAGENTJun 16, 1983
28 days to decisionK831618 · Product code: **GKR** · Hematology
Source: <https://www.510kdatabase.net/k831618/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemoglobin, Automated (GKR)
Date received	May 19, 1983
Decision date	Jun 16, 1983
Days to decision	28 days
Third-party review	No

APPLICANT

Company	Omega Medical Diagnostics
Location	Mchenry, IL, US
510(k) history	5 submissions · 5 cleared · 1983-1983

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Device record: <https://www.510kdatabase.net/k831618/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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