

K894951 MODIFIED HEMOGLOBIN REAGENT SETOct 24, 1989
96 days to decisionK894951 · Product code: **GKK** · Hematology
Source: <https://www.510kdatabase.net/k894951/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cyanomethemoglobin (GKK)
Date received	Jul 20, 1989
Decision date	Oct 24, 1989
Days to decision	96 days
Third-party review	No

APPLICANT

Company	Macomb Biotechnology, Inc.
Location	Romeo, MI, US
Contact	PEGGY MOUNTS
510(k) history	2 submissions · 2 cleared · 1987-1989

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