

K771814 REAGENT CONFIDENCE SERANov 7, 1977
41 days to decisionK771814 · Product code: **KSF** · Hematology
Source: <https://www.510kdatabase.net/k771814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Quality Control For Blood Banking Reagents (KSF)
Date received	Sep 27, 1977
Decision date	Nov 7, 1977
Days to decision	41 days
Third-party review	No

APPLICANT

Company	Ortho Diagnostics, Inc.
Location	Mchenry, IL, US
510(k) history	24 submissions · 24 cleared · 1977-1980

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Device record: <https://www.510kdatabase.net/k771814/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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