

K781573 ABNORMAL HEMATOLOGY CONTROL UNASSAYEDOct 17, 1978
33 days to decisionK781573 · Product code: **JPK** · Hematology
Source: <https://www.510kdatabase.net/k781573/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Sep 14, 1978
Decision date	Oct 17, 1978
Days to decision	33 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/k781573/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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