

K781146 HEMAC LASER HEMATOLOGY SYSTEMSep 14, 1978
66 days to decisionK781146 · Product code: **GKL** · Hematology
Source: <https://www.510kdatabase.net/k781146/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Jul 10, 1978
Decision date	Sep 14, 1978
Days to decision	66 days
Third-party review	No

APPLICANT

Company	Ortho Instruments
Location	Mchenry, IL, US
510(k) history	6 submissions · 6 cleared · 1978-1980

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Device record: <https://www.510kdatabase.net/k781146/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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