

K802094 ORTHO SPECTRUMOct 10, 1980
38 days to decisionK802094 · Product code: **GKL** · Hematology
Source: <https://www.510kdatabase.net/k802094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Sep 2, 1980
Decision date	Oct 10, 1980
Days to decision	38 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/k802094/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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