

K812002 ELUAIDOct 28, 1981
106 days to decisionK812002 · Product code: **GGK** · Hematology
Source: <https://www.510kdatabase.net/k812002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Products, Red-cell Lysing Products (GGK)
Date received	Jul 14, 1981
Decision date	Oct 28, 1981
Days to decision	106 days
Third-party review	No

APPLICANT

Company	Ortho Diagnostic Systems, Inc.
Location	Carpinteria, CA, US
510(k) history	126 submissions · 126 cleared · 1981-1997

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Device record: <https://www.510kdatabase.net/k812002/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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