

K802521 CK-MB(IMMUNOLOGICAL)Nov 12, 1980
28 days to decisionK802521 · Product code: **JHS** · Hematology
Source: <https://www.510kdatabase.net/k802521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Differential Rate Kinetic Method, Cpk Or Isoenzymes (JHS)
Date received	Oct 15, 1980
Decision date	Nov 12, 1980
Days to decision	28 days
Third-party review	No

APPLICANT

Company	Biodynamics Corp.
Location	Walker, MI, US
510(k) history	21 submissions · 21 cleared · 1980-2006

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Device record: <https://www.510kdatabase.net/k802521/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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