

K823388 TENS MAXJan 8, 1983
54 days to decisionK823388 · Product code: **GFK** · Hematology
Source: <https://www.510kdatabase.net/k823388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen Determination Standards And Controls (GFK)
Date received	Nov 15, 1982
Decision date	Jan 8, 1983
Days to decision	54 days
Third-party review	No

APPLICANT

Company	Fujisawa Electronics Co.
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1983-1983

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Device record: <https://www.510kdatabase.net/k823388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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