FDA 510(k) Premarket Notification

# K834571 FIBRINOGEN TEST

**CLEARED**

Feb 4, 1984
37 days to decision

K834571 · Product code: **KQJ** · Hematology
Source: https://www.510kdatabase.net/k834571/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Fibrinogen Determination (KQJ) |
| Date received | Dec 29, 1983 |
| Decision date | Feb 4, 1984 |
| Days to decision | 37 days |
| Third-party review | No |

## APPLICANT

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|---|---|
| Company | **Diatech, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 17 submissions · 17 cleared · 1984-1988 |