FDA 510(k) Premarket Notification

# K812108 LOW FIBRINOGEN CONTROL

**CLEARED**

Sep 24, 1981
59 days to decision

K812108 · Product code: **KQJ** · Hematology
Source: https://www.510kdatabase.net/k812108/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Fibrinogen Determination (KQJ) |
| Date received | Jul 27, 1981 |
| Decision date | Sep 24, 1981 |
| Days to decision | 59 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Bio/Data Corp.** |
| Location | Mchenry, IL, US |
| 510(k) history | 37 submissions · 37 cleared · 1977-2000 |