

**K941001 ENZIP IMMUNOTURBIDMETRIC FIBRINOGEN ASSAY
KIT**Aug 30, 1994
182 days to decisionK941001 · Product code: **GIS** · Hematology
Source: <https://www.510kdatabase.net/k941001/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test, Fibrinogen (GIS) |
| Date received | Mar 1, 1994 |
| Decision date | Aug 30, 1994 |
| Days to decision | 182 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Diagnostic Specialties |
| Location | Mchenry, IL, US |
| Contact | RINALDO PAGNUCCO |
| 510(k) history | 8 submissions · 8 cleared · 1981-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k941001/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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