FDA 510(k) Premarket Notification

# K040359 HEMOSIL SPECIAL TEST CONTROLS LEVEL 1 & 2

**CLEARED**

Mar 19, 2004
35 days to decision

K040359 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k040359/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Multipurpose For In Vitro Coagulation Studies (JPA) |
| Date received | Feb 13, 2004 |
| Decision date | Mar 19, 2004 |
| Days to decision | 35 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Instrumentation Laboratory CO** |
| Location | Mchenry, IL, US |
| Contact | CAROL MARBLE |
| 510(k) history | 321 submissions · 320 cleared · 1976-2023 |