FDA 510(k) Premarket Notification

# K885035 KOAGULAB* 32-S COAGULATION SYSTEM

**CLEARED**

Feb 3, 1989
60 days to decision

K885035 · Product code: **GKP** · Hematology
Source: https://www.510kdatabase.net/k885035/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Coagulation, Automated (GKP) |
| Date received | Dec 5, 1988 |
| Decision date | Feb 3, 1989 |
| Days to decision | 60 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Ortho Diagnostic Systems, Inc.** |
| Location | Carpinteria, CA, US |
| Contact | PATRICIA BONNESS |
| 510(k) history | 126 submissions · 126 cleared · 1981-1997 |