FDA 510(k) Premarket Notification

# K932011 PATHROMTIN

**CLEARED**

Oct 25, 1993
185 days to decision

K932011 · Product code: **GFO** · Hematology
Source: https://www.510kdatabase.net/k932011/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Activated Partial Thromboplastin (GFO) |
| Date received | Apr 23, 1993 |
| Decision date | Oct 25, 1993 |
| Days to decision | 185 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Behring Diagnostics, Inc.** |
| Location | Mchenry, IL, US |
| Contact | JOSEPH KICEINA |
| 510(k) history | 145 submissions · 145 cleared · 1976-1997 |