FDA 510(k) Premarket Notification

# K890052 BIOTRACK APTT REAGENT CARTRIDGE

**CLEARED**

Feb 24, 1989
49 days to decision

K890052 · Product code: **GFO** · Hematology
Source: https://www.510kdatabase.net/k890052/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Activated Partial Thromboplastin (GFO) |
| Date received | Jan 6, 1989 |
| Decision date | Feb 24, 1989 |
| Days to decision | 49 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Biotrack, Inc.** |
| Location | Sunnyvale, CA, US |
| Contact | LAURA WINFREY |
| 510(k) history | 16 submissions · 16 cleared · 1986-1993 |