FDA 510(k) Premarket Notification

# K890883 ABUSCREEN FP BUFFER REAGENT

**CLEARED**

Mar 15, 1989
22 days to decision

K890883 · Product code: **DIO** · Toxicology
Source: https://www.510kdatabase.net/k890883/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO) |
| Date received | Feb 21, 1989 |
| Decision date | Mar 15, 1989 |
| Days to decision | 22 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |

## APPLICANT

| | |
|---|---|
| Company | **Roche Diagnostic Systems, Inc.** |
| Location | Mchenry, IL, US |
| Contact | ALEX WESOLOWSKI |
| 510(k) history | 296 submissions · 296 cleared · 1983-1999 |