FDA 510(k) Premarket Notification

K890884 ABUSCREEN FP FOR BARBITURATES

CLEARED

Mar 9, 1989
16 days to decision

K890884 · Product code: **DIS** · Toxicology
Source: https://www.510kdatabase.net/k890884/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Feb 21, 1989
Decision date	Mar 9, 1989
Days to decision	16 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