FDA 510(k) Premarket Notification

K910589 ABUSCREEN FP FOR CANNABINOIDS (50-100)

CLEARED

Apr 3, 1991
50 days to decision

K910589 · Product code: **LDJ** · Toxicology
Source: https://www.510kdatabase.net/k910589/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cannabinoids (LDJ)
Date received	Feb 12, 1991
Decision date	Apr 3, 1991
Days to decision	50 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