

K910590 ABUSCREEN ONTRAK FOR BENZODIAZEPINEApr 5, 1991
52 days to decisionK910590 · Product code: **JXM** · Toxicology
Source: <https://www.510kdatabase.net/k910590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Benzodiazepine (JXM)
Date received	Feb 12, 1991
Decision date	Apr 5, 1991
Days to decision	52 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

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