

K890884 ABUSCREEN FP FOR BARBITURATESMar 9, 1989
16 days to decisionK890884 · 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

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Device record: <https://www.510kdatabase.net/k890884/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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