

K893855 ABUSCREEN ONTRAK POS. REF. CONTROL FOR BARBITUATESAug 3, 1989
70 days to decisionK893855 · Product code: **LAS** · Toxicology
Source: <https://www.510kdatabase.net/k893855/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Specific Control Materials (LAS)
Date received	May 25, 1989
Decision date	Aug 3, 1989
Days to decision	70 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k893855/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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