

K894464 ABUSCREEN POSITIVE REFERENCE CONTROLSAug 28, 1989
39 days to decisionK894464 · Product code: **LAS** · Toxicology
Source: <https://www.510kdatabase.net/k894464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Specific Control Materials (LAS)
Date received	Jul 20, 1989
Decision date	Aug 28, 1989
Days to decision	39 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/k894464/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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