

**K894463 ABUSCREEN TRI-LEVEL REFERENCE CONTROLS**Aug 21, 1989  
32 days to decisionK894463 · Product code: **LAS** · Toxicology  
Source: <https://www.510kdatabase.net/k894463/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Specific Control Materials (LAS)
Date received	Jul 20, 1989
Decision date	Aug 21, 1989
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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Company	<b>Roche Diagnostic Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	ALEX WESOLOWSKI
510(k) history	296 submissions · 296 cleared · 1983-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894463/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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