

**K951319 ROCHE ABUSCREEN ONLINE FOR OPIATES 1000
TEST KIT-2000 NG/ML CUTOFF OLYMPUS AU800 INSTRUMENT
APPLICATION**Jun 1, 1995
70 days to decisionK951319 · Product code: **DOE** · Toxicology
Source: <https://www.510kdatabase.net/k951319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Morphine (125-i), Goat Antibody Ammonium Sulfate Sep. (DOE)
Date received	Mar 23, 1995
Decision date	Jun 1, 1995
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	CAROL L KRIEGER
510(k) history	296 submissions · 296 cleared · 1983-1999

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