

K905730 ABUSCREEN ONTRAK FOR COCAINE (200NG/ML)Jan 15, 1991
22 days to decisionK905730 · Product code: **KLN** · Toxicology
Source: <https://www.510kdatabase.net/k905730/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Cocaine Metabolite (KLN)
Date received	Dec 24, 1990
Decision date	Jan 15, 1991
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No

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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Device record: <https://www.510kdatabase.net/k905730/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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