

K912756 ABUSCREEN RADIOIMMUNOASSAY FOR COCAINE METABOLITEJul 26, 1991
35 days to decisionK912756 · Product code: **KLN** · Toxicology
Source: <https://www.510kdatabase.net/k912756/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Cocaine Metabolite (KLN) |
| Date received | Jun 21, 1991 |
| Decision date | Jul 26, 1991 |
| Days to decision | 35 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | 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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