

K853010 COBAS REAGENT FOR LIDOCAINE & CALIBRATORSAug 7, 1985
22 days to decisionK853010 · Product code: **KLR** · Toxicology
Source: <https://www.510kdatabase.net/k853010/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Lidocaine (KLR) |
| Date received | Jul 16, 1985 |
| Decision date | Aug 7, 1985 |
| 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 | KAFADER II |
| 510(k) history | 296 submissions · 296 cleared · 1983-1999 |

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