

K060773 ONLINE TDM PROCAINAMIDEAug 23, 2006
154 days to decisionK060773 · Product code: **LAR** · Toxicology
Source: <https://www.510kdatabase.net/k060773/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Procainamide (LAR) |
| Date received | Mar 22, 2006 |
| Decision date | Aug 23, 2006 |
| Days to decision | 154 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Roche Diagnostics Corp. |
| Location | Indianapolis, IN, US |
| Contact | DIMITRIS DEMIRTZOGLU |
| 510(k) history | 264 submissions · 263 cleared · 1999-2013 |

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