

K833384 PROCAINAMIDE ANALYTICAL TEST PACKDec 27, 1983
89 days to decisionK833384 · Product code: **LAR** · Chemistry
Source: <https://www.510kdatabase.net/k833384/>**SUBMISSION DETAILS**

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|-----------------------|----------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Procainamide (LAR) |
| Date received | Sep 29, 1983 |
| Decision date | Dec 27, 1983 |
| Days to decision | 89 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|-----------------------------------------------|
| Company | E.I. Dupont DE Nemours & Co., Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 253 submissions · 252 cleared · 1976-1996 |

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