

K811618 EMIT-CAD PROCAINAMIDE/N-ACETYL. CONTROLJun 25, 1981
17 days to decisionK811618 · Product code: **DIF** · Toxicology
Source: <https://www.510kdatabase.net/k811618/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Drug Mixture Control Materials (DIF) |
| Date received | Jun 8, 1981 |
| Decision date | Jun 25, 1981 |
| Days to decision | 17 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |

APPLICANT

| | |
|----------------|---|
| Company | Syva Co. |
| Location | Mchenry, IL, US |
| 510(k) history | 448 submissions · 447 cleared · 1976-2001 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k811618/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026