

K820296 STRATUS TDM CONTROL, LEVELS I,II,IIIMay 14, 1982
99 days to decisionK820296 · Product code: **DIF** · Chemistry
Source: <https://www.510kdatabase.net/k820296/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Drug Mixture Control Materials (DIF) |
| Date received | Feb 4, 1982 |
| Decision date | May 14, 1982 |
| Days to decision | 99 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | American Dade |
| Location | Mchenry, IL, US |
| 510(k) history | 149 submissions · 149 cleared · 1980-1987 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k820296/> 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 May 14, 2026