

K822237 UREA NITROGEN REAGENT SET (MOD. BERTHELAug 16, 1982
19 days to decisionK822237 · Product code: **CDL** · Chemistry
Source: <https://www.510kdatabase.net/k822237/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Berthelot Indophenol, Urea Nitrogen (CDL) |
| Date received | Jul 28, 1982 |
| Decision date | Aug 16, 1982 |
| Days to decision | 19 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Sterling Biochemical, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 15 submissions · 15 cleared · 1982-1985 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k822237/> 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 July 4, 2026