

**K853244 TOTAL PROTEIN REAGENT FOR ASTRA 8 STAT/ROU
ANALYZE**Aug 12, 1985
11 days to decisionK853244 · Product code: **CEK** · Chemistry
Source: <https://www.510kdatabase.net/k853244/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Biuret (colorimetric), Total Protein (CEK) |
| Date received | Aug 1, 1985 |
| Decision date | Aug 12, 1985 |
| Days to decision | 11 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Simmler, Inc. |
| Location | Mchenry, IL, US |
| Contact | BOEDEKER |
| 510(k) history | 23 submissions · 23 cleared · 1980-1989 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853244/>; 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 29, 2026