

**K896916 CLINISTAT TOTAL PROTEIN REAGENT TEST**Jan 19, 1990  
39 days to decisionK896916 · Product code: **CEK** · Chemistry  
Source: <https://www.510kdatabase.net/k896916/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)         |
| Submission type       | Traditional                                |
| Device classification | Biuret (colorimetric), Total Protein (CEK) |
| Date received         | Dec 11, 1989                               |
| Decision date         | Jan 19, 1990                               |
| Days to decision      | 39 days                                    |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Heraeus Kulzer, Inc.</b>               |
| Location       | Elkhart, IN, US                           |
| Contact        | ROSANNE SAVOL                             |
| 510(k) history | 145 submissions · 145 cleared · 1988-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k896916/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 20, 2026