

**K905661 SYSTEMATE TOTAL PROTEIN (EPOS APPLICATION)  
#65420**Jan 31, 1991  
44 days to decisionK905661 · Product code: **CEK** · Chemistry  
Source: <https://www.510kdatabase.net/k905661/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)         |
| Submission type       | Traditional                                |
| Device classification | Biuret (colorimetric), Total Protein (CEK) |
| Date received         | Dec 18, 1990                               |
| Decision date         | Jan 31, 1991                               |
| Days to decision      | 44 days                                    |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Em Diagnostic Systems, Inc.</b>        |
| Location       | Walker, MI, US                            |
| Contact        | ANNA G BENTLEY                            |
| 510(k) history | 288 submissions · 288 cleared · 1984-1994 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905661/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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