

K893915 EMDS TOTAL PROTEIN (TP), ITEM NUMBER 65420Aug 31, 1989
93 days to decisionK893915 · Product code: **CEK** · Chemistry
Source: <https://www.510kdatabase.net/k893915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biuret (colorimetric), Total Protein (CEK)
Date received	May 30, 1989
Decision date	Aug 31, 1989
Days to decision	93 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k893915/>; 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