

K915380 MICROPROTEIN-PRFeb 18, 1992
81 days to decisionK915380 · Product code: **CEK** · Chemistry
Source: <https://www.510kdatabase.net/k915380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biuret (colorimetric), Total Protein (CEK)
Date received	Nov 29, 1991
Decision date	Feb 18, 1992
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k915380/> 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