

K860138 NO. 615 DETERMINATION OF CERULOPLASMIN IN SERUMMar 28, 1986
73 days to decisionK860138 · Product code: **DDB** · Immunology
Source: <https://www.510kdatabase.net/k860138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ceruloplasmin, Antigen, Antiserum, Control (DDB)
Date received	Jan 14, 1986
Decision date	Mar 28, 1986
Days to decision	73 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860138/>; 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