

K053074 N ANTISERA TO HUMAN CERULOPLASMINMar 16, 2006
135 days to decisionK053074 · Product code: **DDB** · Immunology
Source: <https://www.510kdatabase.net/k053074/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ceruloplasmin, Antigen, Antiserum, Control (DDB)
Date received	Nov 1, 2005
Decision date	Mar 16, 2006
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	KATHLEEN A DRAY-LYONS
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053074/> 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 June 19, 2026