FDA 510(k) Premarket Notification

K053074 N ANTISERA TO HUMAN CERULOPLASMIN

CLEARED

Mar 16, 2006
135 days to decision

K053074 · 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