

**K050665 N ANTISERA TO HUMAN COMPLEMENT FACTORS
(C3C, C4)**

May 2, 2005
48 days to decision

K050665 · Product code: **CZW** · Immunology
Source: <https://www.510kdatabase.net/k050665/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C3, Antigen, Antiserum, Control (CZW)
Date received	Mar 15, 2005
Decision date	May 2, 2005
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k050665/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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