

**K964842 IMAGE IMMUNOCHEMISTRY SYSTEM  
COMPLEMENTC3 (C3) AND COMPLEMENTC4 (C4) REAGENT**Jun 11, 1997  
190 days to decisionK964842 · Product code: **CZW** · Immunology  
Source: <https://www.510kdatabase.net/k964842/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C3, Antigen, Antiserum, Control (CZW)
Date received	Dec 3, 1996
Decision date	Jun 11, 1997
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beckman Instruments, Inc.</b>
Location	Mchenry, IL, US
Contact	MARGIE GEORGE
Website	<a href="https://www.beckman.com">https://www.beckman.com</a>
510(k) history	281 submissions · 281 cleared · 1976-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964842/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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