

**K964843 IMAGE IMMUNOCHEMISTRY SYSTEM PROPERDIN  
FACTOR B (PFB) REAGENT**Mar 6, 1997  
93 days to decisionK964843 · Product code: JZH · Immunology  
Source: <https://www.510kdatabase.net/k964843/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Factor B, Antigen, Antiserum, Control (JZH)
Date received	Dec 3, 1996
Decision date	Mar 6, 1997
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beckman Instruments, Inc.</b>
Location	Mchenry, IL, US
Contact	ANNETTE HELLIE
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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