

K964297 N-ASSAY TIA C4 TEST KITJul 14, 1997
258 days to decisionK964297 · Product code: **DBI** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C4, Antigen, Antiserum, Control (DBI)
Date received	Oct 29, 1996
Decision date	Jul 14, 1997
Days to decision	258 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Crestat Diagnostics, Inc.
Location	Portland, OR, US
510(k) history	29 submissions · 29 cleared · 1990-1998

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