

K965024 N-ASSAY TIA C1-INACTIVATOR TEST KITJul 14, 1997
209 days to decisionK965024 · Product code: **DBA** · Immunology
Source: <https://www.510kdatabase.net/k965024/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C1 Inhibitor (inactivator), Antigen, Antiserum, Control (DBA)
Date received	Dec 17, 1996
Decision date	Jul 14, 1997
Days to decision	209 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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