

K821898 ORTHO CLASSICAL PATHWAY COMPL. TESTJul 16, 1982
18 days to decisionK821898 · Product code: **DBA** · Immunology
Source: <https://www.510kdatabase.net/k821898/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C1 Inhibitor (inactivator), Antigen, Antiserum, Control (DBA)
Date received	Jun 28, 1982
Decision date	Jul 16, 1982
Days to decision	18 days
Third-party review	No

APPLICANT

Company	Ortho Diagnostic Systems, Inc.
Location	Carpinteria, CA, US
510(k) history	126 submissions · 126 cleared · 1981-1997

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