

K853025 IMAGE-IGEAug 22, 1985
35 days to decisionK853025 · Product code: **DGC** · Immunology
Source: <https://www.510kdatabase.net/k853025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Jul 18, 1985
Decision date	Aug 22, 1985
Days to decision	35 days
Third-party review	No

APPLICANT

Company	Clinical Reference Laboratory, Inc.
Location	Lenexa, KA, US
510(k) history	1 submissions · 1 cleared · 1985-1985

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Device record: <https://www.510kdatabase.net/k853025/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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