

K910419 BIOCLONE'S ELEGANCE IGE ELISA KITJun 21, 1991
142 days to decisionK910419 · Product code: **DGC** · Immunology
Source: <https://www.510kdatabase.net/k910419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Jan 30, 1991
Decision date	Jun 21, 1991
Days to decision	142 days
Third-party review	No

APPLICANT

Company	Bioclone Australia Pty , Ltd.
Location	Washington, DC, US
Contact	BRUCE F MACKLER
510(k) history	10 submissions · 10 cleared · 1990-1994

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