

K910420 BIOCLONE'S ELEGANCE HCG ELISA KITFeb 26, 1991
27 days to decisionK910420 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k910420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jan 30, 1991
Decision date	Feb 26, 1991
Days to decision	27 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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