

K904405 BIOCLONES ELEGANCE FSH ELISA KITOct 26, 1990
31 days to decisionK904405 · Product code: **CGJ** · Chemistry
Source: <https://www.510kdatabase.net/k904405/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Sep 25, 1990
Decision date	Oct 26, 1990
Days to decision	31 days
Third-party review	No

APPLICANT

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

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