

K922284 ELEGANCE FT4 ELISAJul 10, 1992
56 days to decisionK922284 · Product code: **CEC** · Chemistry
Source: <https://www.510kdatabase.net/k922284/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Free Thyroxine (CEC)
Date received	May 15, 1992
Decision date	Jul 10, 1992
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

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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