

K904483 ELEGANCE PROLACTIN ELISANov 5, 1990
34 days to decisionK904483 · Product code: **CFT** · Chemistry
Source: <https://www.510kdatabase.net/k904483/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Prolactin (lactogen) (CFT) |
| Date received | Oct 2, 1990 |
| Decision date | Nov 5, 1990 |
| Days to decision | 34 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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