

K781546 DIRECT ESTRIOL RIA KITDec 4, 1978
82 days to decisionK781546 · Product code: **CGI** · Chemistry
Source: <https://www.510kdatabase.net/k781546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estriol (CGI)
Date received	Sep 13, 1978
Decision date	Dec 4, 1978
Days to decision	82 days
Third-party review	No

APPLICANT

Company	Immunalysis Corporation
Location	Mchenry, IL, US
510(k) history	50 submissions · 50 cleared · 1978-2025

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Device record: <https://www.510kdatabase.net/k781546/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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