

K860823 ELSA-PROL IMMUNORADIOMETRIC ASSAY KITAug 19, 1986
168 days to decisionK860823 · Product code: **CFT** · Chemistry
Source: <https://www.510kdatabase.net/k860823/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Prolactin (lactogen) (CFT)
Date received	Mar 4, 1986
Decision date	Aug 19, 1986
Days to decision	168 days
Third-party review	No

APPLICANT

Company	Cis-U.S, Inc.
Location	Lake Success, NY, US
Contact	MICHAEL D GARRETT
510(k) history	9 submissions · 9 cleared · 1986-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860823/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 21, 2026