

K913280 OPUS(R) PROLACTIN TEST SYSTEMAug 16, 1991
23 days to decisionK913280 · Product code: **CFT** · Toxicology
Source: <https://www.510kdatabase.net/k913280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Prolactin (lactogen) (CFT)
Date received	Jul 24, 1991
Decision date	Aug 16, 1991
Days to decision	23 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pb Diagnostic Systems, Inc.
Location	Westwood, MA, US
Contact	LORI BARANAUSKAS
510(k) history	35 submissions · 35 cleared · 1988-1994

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