

K940507 OPUS FT4 TEST SYSTEMJul 28, 1994
176 days to decisionK940507 · Product code: **CEC** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Free Thyroxine (CEC)
Date received	Feb 2, 1994
Decision date	Jul 28, 1994
Days to decision	176 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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