

K911409 OPUS FSHApr 16, 1991
15 days to decisionK911409 · Product code: **CGJ** · Toxicology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Apr 1, 1991
Decision date	Apr 16, 1991
Days to decision	15 days
Third-party review	No

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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