

K974508 DBEST ONE-STEP OVULATION TESTFeb 2, 1998
63 days to decisionK974508 · Product code: **CEP** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Dec 1, 1997
Decision date	Feb 2, 1998
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ameritek, Inc.
Location	Miami, FL, US
Contact	KUO CHIANG YEE
510(k) history	17 submissions · 17 cleared · 1986-2000

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