

K970467 EZ SURE ONE STEP OVULATION PREDICTOR HOME TEST KIT

Mar 18, 1997
39 days to decision

K970467 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k970467/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Feb 7, 1997
Decision date	Mar 18, 1997
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Excel Scientific, Inc.
Location	Yorba Linda, CA, US
Contact	MIN-LEE CHENG
510(k) history	8 submissions · 8 cleared · 1996-1997

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k970467/>; 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 June 30, 2026