

K861354 RIGHT-DAY OVULATION HOME TESTSep 16, 1986
159 days to decisionK861354 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k861354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Apr 10, 1986
Decision date	Sep 16, 1986
Days to decision	159 days
Third-party review	No

APPLICANT

Company	Leeco Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	LEE, PH.D.
510(k) history	49 submissions · 49 cleared · 1979-1989

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