

**K991466 EARLY OVULATION PREDICTOR (CASSETTE), ONE  
STEP OVULATION PREDICTOR (CASSETTE), OVULATION  
PREDICTOR (CASSETTE)**May 25, 1999  
28 days to decisionK991466 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k991466/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Apr 27, 1999
Decision date	May 25, 1999
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Selfcare, Inc.</b>
Location	Waltham, MA, US
Contact	Carol Adiletto
510(k) history	15 submissions · 15 cleared · 1996-2000

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