

K002867 INVERNESS MEDICAL OVULATION PREDICTOR TESTOct 12, 2000
29 days to decisionK002867 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k002867/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Radioimmunoassay, Luteinizing Hormone (CEP) |
| Date received | Sep 13, 2000 |
| Decision date | Oct 12, 2000 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Selfcare, Inc. |
| Location | Waltham, MA, US |
| Contact | CAROL A ADILETTO |
| 510(k) history | 15 submissions · 15 cleared · 1996-2000 |

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