

**K041240 SEMEN ANALYSIS QUALITY CONTROL, ASSAYED  
AND UNASSAYED**Jun 2, 2004  
22 days to decisionK041240 · Product code: **NRF** · Hematology  
Source: <https://www.510kdatabase.net/k041240/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Material, Quality Control, Semen Analysis (NRF) |
| Date received         | May 11, 2004                                    |
| Decision date         | Jun 2, 2004                                     |
| Days to decision      | 22 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Fertility Solutions, Inc.</b>      |
| Location       | Cleveland, OH, US                     |
| Contact        | SUSAN A ROTHMANN, PH.D., HCLD         |
| 510(k) history | 1 submissions · 1 cleared · 2004-2004 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041240/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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