

**K082091 TRI T-STAT REAGENT ASSAY (DRIED FORM) MODEL  
25107-00**

Apr 15, 2009  
265 days to decision

K082091 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k082091/>

**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Counter, Differential Cell (GKZ)   |
| Date received         | Jul 24, 2008                       |
| Decision date         | Apr 15, 2009                       |
| Days to decision      | 265 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Reamatrix, Inc.</b>                |
| Location       | San Carlos, CA, US                    |
| Contact        | STEVE KUNITAKE                        |
| 510(k) history | 1 submissions · 1 cleared · 2009-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k082091/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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