

K072905 3TEST SUPREME GLUCOSE MONITORING SYSTEMApr 18, 2008
190 days to decisionK072905 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k072905/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Blood Glucose, Over The Counter (NBW) |
| Date received | Oct 11, 2007 |
| Decision date | Apr 18, 2008 |
| Days to decision | 190 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Neuro Engineering, Inc. |
| Location | Hsin-Chu City, TW |
| Contact | Ke-Min Jen |
| 510(k) history | 2 submissions · 2 cleared · 2005-2008 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072905/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 25, 2026