

K123559 SOLUSMOBILE BLOOD GLUCOSE MANAGMENT SYSTEMJun 28, 2013
221 days to decisionK123559 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k123559/>**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 | Nov 19, 2012 |
| Decision date | Jun 28, 2013 |
| Days to decision | 221 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biotest Medical Corp. |
| Location | Fairfax, VA, US |
| Contact | FRED LEE |
| 510(k) history | 8 submissions · 8 cleared · 2009-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123559/> 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 4, 2026