

**K081478 RNA MEDICAL GLUCOSE AND B-KETONE
CALIBRATION VERIFICATION CONTROLS**Oct 6, 2008
132 days to decisionK081478 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k081478/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received | May 27, 2008 |
| Decision date | Oct 6, 2008 |
| Days to decision | 132 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Bionostics, Inc. |
| Location | Mchenry, IL, US |
| Contact | KATHLEEN STORRO |
| 510(k) history | 49 submissions · 49 cleared · 1983-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081478/>; 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 9, 2026