

**K122688 NOVA MAX MINI BLOOD GLUCOSE AND B-KETONE MONITOR**Apr 4, 2013  
212 days to decisionK122688 · Product code: LFR · Chemistry  
Source: <https://www.510kdatabase.net/k122688/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Glucose Dehydrogenase, Glucose (LFR) |
| Date received         | Sep 4, 2012                          |
| Decision date         | Apr 4, 2013                          |
| Days to decision      | 212 days                             |
| Third-party review    | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|----------------|---|
| Company        | <b>Nova Biomedical Corporation</b>      |
| Location       | Waltham, MA, US                         |
| Contact        | PAUL W MACDONALD                        |
| 510(k) history | 40 submissions · 40 cleared · 2011-2026 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122688/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026