

**K970710 STAT PROFILE ULTRA M ANALYZER**May 9, 1997  
72 days to decisionK970710 · Product code: **CHL** · Chemistry  
Source: <https://www.510kdatabase.net/k970710/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                |
| Submission type       | Traditional   |
| Device classification | Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL) |
| Date received         | Feb 26, 1997  |
| Decision date         | May 9, 1997   |
| Days to decision      | 72 days   |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Nova Biomedical Corp.</b>            |
| Location       | Mchenry, IL, US                         |
| Contact        | PAUL W MACDONALD                        |
| 510(k) history | 89 submissions · 89 cleared · 1977-2011 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970710/> 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 18, 2026