

**K832527 PREGNA-TEC**Sep 12, 1983  
45 days to decisionK832527 · Product code: **JHJ** · Chemistry  
Source: <https://www.510kdatabase.net/k832527/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                       |
| Submission type       | Traditional  |
| Device classification | Agglutination Method, Human Chorionic Gonadotropin (JHJ) |
| Date received         | Jul 29, 1983   |
| Decision date         | Sep 12, 1983   |
| Days to decision      | 45 days  |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Medilab Corp.</b>                  |
| Location       | Mchenry, IL, US                       |
| 510(k) history | 7 submissions · 7 cleared · 1983-1984 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k832527/> 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 29, 2026