

**K873064 AMTEC RHEUMATOID FACTOR LATEX  
AGGLUTINATION KIT**Nov 4, 1987  
91 days to decisionK873064 · Product code: **DHR** · Immunology  
Source: <https://www.510kdatabase.net/k873064/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | System, Test, Rheumatoid Factor (DHR) |
| Date received         | Aug 5, 1987                           |
| Decision date         | Nov 4, 1987                           |
| Days to decision      | 91 days                               |
| Third-party review    | No                                    |

**APPLICANT**

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|----------------|--|
| Company        | <b>Amtec Diagnostics International, Inc.</b> |
| Location       | Conroe, TX, US                               |
| Contact        | HELEN JOHNSON                                |
| 510(k) history | 2 submissions · 2 cleared · 1987-1988        |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k873064/>; 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 30, 2026