

**K905038 OLYMPUS PK-TP ABSORBENT KIT**May 6, 1991  
181 days to decisionK905038 · Product code: **GMT** · Microbiology  
Source: <https://www.510kdatabase.net/k905038/>**SUBMISSION DETAILS**

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|                       |                                        |
|-----------------------|----------------------------------------|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Antigens, Ha, Treponema Pallidum (GMT) |
| Date received         | Nov 6, 1990                            |
| Decision date         | May 6, 1991                            |
| Days to decision      | 181 days                               |
| Third-party review    | No                                     |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Fujirebio America, Inc.</b>        |
| Location       | Fairfield, NJ, US                     |
| Contact        | RICHARD H ARNETTE                     |
| 510(k) history | 2 submissions · 2 cleared · 1991-1995 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905038/>; 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