

**K972389 VISTA ANTIGEN SALMONELLA H D**Aug 25, 1997  
60 days to decisionK972389 · Product code: **GNC** · Microbiology  
Source: <https://www.510kdatabase.net/k972389/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                                   |
| Submission type       | Traditional  |
| Device classification | Antigens, Febrile, Slide And Tube, All Groups, Salmonella Spp. (GNC) |
| Date received         | Jun 26, 1997   |
| Decision date         | Aug 25, 1997   |
| Days to decision      | 60 days  |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Lee Laboratories, Inc.</b>           |
| Location       | Grayson, GA, US                         |
| Contact        | ROBIN C HART                            |
| 510(k) history | 10 submissions · 10 cleared · 1997-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972389/> 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