

K972388 VISTA ANTIGEN SALMONELLA O GROUP CAug 25, 1997
60 days to decisionK972388 · Product code: **GNC** · Microbiology
Source: <https://www.510kdatabase.net/k972388/>**SUBMISSION DETAILS**

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

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972388/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026