

**K991268 GONOSTAT GONOCOCCAL DETECTION KIT**Aug 11, 1999  
120 days to decisionK991268 · Product code: **LSL** · Microbiology  
Source: <https://www.510kdatabase.net/k991268/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Apr 13, 1999
Decision date	Aug 11, 1999
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sierra Diagnostics</b>
Location	Washington, DC, US
Contact	DONALD R STONE
510(k) history	1 submissions · 1 cleared · 1999-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991268/> 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