

**K894122 LEECO VIS-DISK STREP-A (EIA)**Aug 15, 1989  
64 days to decisionK894122 · Product code: **GTZ** · Microbiology  
Source: <https://www.510kdatabase.net/k894122/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | Antisera, All Groups, Streptococcus Spp. (GTZ) |
| Date received         | Jun 12, 1989                                   |
| Decision date         | Aug 15, 1989                                   |
| Days to decision      | 64 days  |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Leeco Diagnostics, Inc.</b>          |
| Location       | Mchenry, IL, US                         |
| Contact        | DANTE CAPALDI                           |
| 510(k) history | 49 submissions · 49 cleared · 1979-1989 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894122/>, 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