

**K924715 GEN-PROBE DIRECT GROUP A STREPTOCOCCUS TEST**Mar 11, 1994  
536 days to decisionK924715 · Product code: **MDK** · Microbiology  
Source: <https://www.510kdatabase.net/k924715/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Dna-probe, Reagents, Streptococcal (MDK) |
| Date received         | Sep 21, 1992                             |
| Decision date         | Mar 11, 1994                             |
| Days to decision      | 536 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Gen-Probe, Inc.</b>  |
| Location       | San Diego, CA, US   |
| Contact        | RUBEN CHAIREZ   |
| Website        | <a href="http://www.gen-probe.com">http://www.gen-probe.com</a> |
| 510(k) history | 62 submissions · 62 cleared · 1985-2013                         |

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