

K890089 RAPID DIAG. SYSTEM FOR MYCOBACTERIUM GORDONAEMar 13, 1989
62 days to decisionK890089 · Product code: **LQF** · Microbiology
Source: <https://www.510kdatabase.net/k890089/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dna-reagents, Mycobacterium Spp. (LQF) |
| Date received | Jan 10, 1989 |
| Decision date | Mar 13, 1989 |
| Days to decision | 62 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Gen-Probe, Inc. |
| Location | San Diego, CA, US |
| Contact | BRUNI, PHD |
| Website | http://www.gen-probe.com |
| 510(k) history | 62 submissions · 62 cleared · 1985-2013 |

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