

**K926049 DIGITEX, DIGITEX HYPOALLERGENIC**Jul 22, 1993  
233 days to decisionK926049 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k926049/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 1, 1992
Decision date	Jul 22, 1993
Days to decision	233 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Mayer Laboratories</b>
Location	Oakland, CA, US
Contact	DAVID P MAYER
510(k) history	16 submissions · 16 cleared · 1987-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k926049/> 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 May 20, 2026