

**K891353 PATIENT EXAMINATION GLOVES (LATEX)**Apr 28, 1989  
46 days to decision

K891353 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k891353/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 13, 1989
Decision date	Apr 28, 1989
Days to decision	46 days
Third-party review	No

**APPLICANT**

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Company	<b>Audra, Inc.</b>
Location	Sturgis, MI, US
Contact	AUDRA NOECKER
510(k) history	1 submissions · 1 cleared · 1989-1989

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k891353/>; 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 July 8, 2026