

**K040828 DISPOSABLE POWDERED VINYL PATIENT
EXAMINATION GLOVES**Apr 19, 2004
19 days to decisionK040828 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k040828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Mar 31, 2004
Decision date	Apr 19, 2004
Days to decision	19 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Zibo Borui Plastic & Rubber Products Co., Ltd.
Location	North Billerica, MA, US
Contact	HUAN-CHUNG LI
510(k) history	2 submissions · 2 cleared · 2004-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040828/> Data sourced from FDA 510(k) public records (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. - Generated July 2, 2026