

**K011728 BRIGHTWAY BRAND POWDER FREE LATEX EXAMINATION GLOVES, BLUE NON-STERILE, PROTEIN LABELING CLAIM (50 MICROGRAMS OR LESS) (**Jul 9, 2001  
35 days to decisionK011728 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k011728/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jun 4, 2001
Decision date	Jul 9, 2001
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Brightway Holdings Sdn. Bhd.</b>
Location	Klang, Selangor Darul Ehsan, MY
Contact	G. BASKARAN
510(k) history	24 submissions · 24 cleared · 1999-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011728/> 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 June 1, 2026