

**K201576 Disposable Latex Powder Free Examination Gloves
(Non-sterile)**May 19, 2021
342 days to decisionK201576 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k201576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jun 11, 2020
Decision date	May 19, 2021
Days to decision	342 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Pt. Universal Gloves
Location	Medan, ID
Contact	Sutopo Sutopo
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Ammex Corporation
Contact	Sasitharan Nair

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)