

K163126 Powder Free Nitrile Examination Gloves (Blue, White, Black, Violet Blue, Cobalt blue)

Feb 22, 2017
106 days to decision

K163126 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k163126/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 8, 2016
Decision date	Feb 22, 2017
Days to decision	106 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Blue Sail Medical Co.,Ltd
Location	Zibo, CN
Contact	Robin Liu
510(k) history	2 submissions · 2 cleared · 2017-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163126/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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