

K181106 Powder Free Nitrile Patient Examination Gloves, Blue ColorJan 16, 2019
265 days to decisionK181106 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k181106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 26, 2018
Decision date	Jan 16, 2019
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Dongxin Medical Technology Co., Ltd.
Location	Suqian, CN
Contact	Deng Yujie
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Beijing Easylink Co., Ltd.
Contact	Chu Xiaoan

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181106/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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