

K203622 Medical GlovesAug 20, 2021
252 days to decisionK203622 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k203622/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 11, 2020
Decision date	Aug 20, 2021
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beijing Biosis Healing Biological Technology Co., Ltd.
Location	Beijing, CN
Contact	Ting Jiang
510(k) history	7 submissions · 7 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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/k203622/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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