

K163146 POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy DrugsFeb 13, 2017
96 days to decisionK163146 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k163146/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	Nov 9, 2016
Decision date	Feb 13, 2017
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hebei Hongsen Plastics Technology Co, Ltd.
Location	Pennington, NJ, US
Contact	Shaozhang Nan
510(k) history	5 submissions · 5 cleared · 2013-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163146/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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