FDA 510(k) Premarket Notification

K210730 Nitrile Patient Examination Glove

CLEARED

Aug 10, 2021
152 days to decision

K210730 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k210730/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 11, 2021
Decision date	Aug 10, 2021
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**American Performance Polymers, LLC**
Location	Colebrook, NH, US
Contact	Richard Renehan
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**MEDIcept, Inc.**
Contact	Natalie Vollrath

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k210730/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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