CLEARED

Jul 21, 2023
102 days to decision

K231021 KIMTECH™ Polaris™ Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid

K231021 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k231021/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 10, 2023
Decision date	Jul 21, 2023
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kimberly Clark Corporation**
Location	Neenah, WI, US
Contact	Kimberly Tempas
510(k) history	13 submissions · 12 cleared · 2010-2023

REGULATORY CONSULTANT

Consulting firm	**Pathmaker FDA Law, PLLC**
Contact	Amy Fowler

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