

K202449 Signature Latex LT, Powder-Free, Surgical Glove, Tested for Use with Chemotherapy Drugs with a Protein Content Label Claim of <math><50\mu\text{g}/\text{dm}^2</math> per glove of Extractable Protein

Nov 18, 2020
84 days to decision

K202449 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k202449/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Aug 26, 2020
Decision date	Nov 18, 2020
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Medline Industries, Inc.
Location	Mchenry, IL, US
Contact	Jennifer Mason
510(k) history	238 submissions · 234 cleared · 1977-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k202449/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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