

K202668 Signature Latex and Signature Latex Micro, Powder-Free, Surgical Glove, Tested for Use with Chemotherapy Drugs with a Protein Content Label Claim of <50µg/dm2 per Glove of Extractable Protein

Dec 19, 2020
96 days to decision

K202668 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k202668/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Sep 14, 2020
Decision date	Dec 19, 2020
Days to decision	96 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/k202668/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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