

K203705 Latex Examination Glove, Powder free with Protein Content Labeling Claim (50 ug/g or less of total extractable Protein)

Aug 20, 2021
245 days to decision

K203705 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k203705/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 18, 2020
Decision date	Aug 20, 2021
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Careplus (M) Sdn Bhd
Location	Negeri Sembilan Darul Khusus, MY
Contact	Lim Kwee Shyan
510(k) history	10 submissions · 10 cleared · 2015-2021

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k203705/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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