

K172942 Pristeen (Latex Surgeon's Gloves Powder Free, Polymer coated with protein content labeling claim of 50 ug/dm2 or less per glove of extractable proteinJan 8, 2018
104 days to decisionK172942 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k172942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Surgeon's Gloves (KGO)
Date received	Sep 26, 2017
Decision date	Jan 8, 2018
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beta Healthcare Products Pvt., Ltd.
Location	Kochi, IN
Contact	Boney Moolayil
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172942/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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