

**K171276 Sterile Polyisoprene Surgical Powder Free Glove
Tested for Use with Chemotherapy Drugs**

Aug 21, 2017
112 days to decision

K171276 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k171276/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	May 1, 2017
Decision date	Aug 21, 2017
Days to decision	112 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tg Medical Sdn. Bhd.
Location	Kapar, Selangor D.E., MY
Contact	Fatima Wati BT Mohamad
510(k) history	9 submissions · 9 cleared · 1994-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k171276/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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