

K945505 ACRYLIC DIPPED LATEX SURGICAL GLOVES - STERILE

Aug 18, 1995
282 days to decision

K945505 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k945505/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Nov 9, 1994
Decision date	Aug 18, 1995
Days to decision	282 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ganz Industries Sdn. Bhd.
Location	Nilai 71800, Negeri Sembilan, MY
510(k) history	4 submissions · 4 cleared · 1995-1996

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Device record: <https://www.510kdatabase.net/k945505/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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