FDA 510(k) Premarket Notification

K892061 GRAND GUARD SURGICAL GLOVES

CLEARED

May 23, 1989
54 days to decision

K892061 · Product code: **KGO** · General Hospital
Source: https://www.510kdatabase.net/k892061/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Mar 30, 1989
Decision date	May 23, 1989
Days to decision	54 days
Third-party review	No

APPLICANT

Company	**Galaxy Intl., Inc.**
Location	Salt Lake City, UT, US
Contact	MING CHENG
510(k) history	3 submissions · 3 cleared · 1989-1989

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k892061/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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