

**K964980 ULTREX POWDER-FREE SURGICAL GLOVES/ULTREX
POWDER-FREE SURGICAL GLOVES WITH LOW PROTEIN
CLAIM**Mar 6, 1997
83 days to decisionK964980 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k964980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Dec 13, 1996
Decision date	Mar 6, 1997
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Maxxim Medical
Location	Arlington, TX, US
Contact	JOYCE MOODY
510(k) history	26 submissions · 25 cleared · 1994-2002

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