

**K071746 DERMA PRENE PI OR ISOTOUCH GREEN STERILE
POWDER-FREE SYNTHETIC POLYISOPRENE SURGICAL
GLOVES**

Dec 13, 2007
169 days to decision

K071746 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k071746/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jun 27, 2007
Decision date	Dec 13, 2007
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ansell Healthcare Products, LLC
Location	Dothan, AL, US
Contact	CYNTHIA A INGRAM
510(k) history	26 submissions · 26 cleared · 2005-2023

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Device record: <https://www.510kdatabase.net/k071746/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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