

K111139 DERMA PRENE ISOTOUCH GREEN STERILE POWDER-FREE POLYISOPRENE SURGICAL GLOVES, TESTED FOR USep 2, 2011
133 days to decisionK111139 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k111139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Apr 22, 2011
Decision date	Sep 2, 2011
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ansell Healthcare Products, Inc.
Location	Massillon, OH, US
Contact	NEIL BURRIS
510(k) history	10 submissions · 10 cleared · 2000-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111139/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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