

K190077 Biogel® PI UltraTouch S Surgical Glove, Biogel® PI Ultra Touch S Indicator UndergloveMay 24, 2019
128 days to decisionK190077 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k190077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jan 16, 2019
Decision date	May 24, 2019
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Molnlycke Health Care Us, LLC
Location	Norcross, GA, US
Contact	Leonard Stewart
510(k) history	27 submissions · 27 cleared · 2006-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190077/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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