

**K191869 Biogel(R) PI UltraTouch S Surgical Glove with a Low Dermatitis Potential Claim, Biogel(R) PI UltraTouch S Indicator Underglove with a Low Dermatitis Potential Claim**

Mar 13, 2020  
245 days to decision

K191869 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k191869/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Jul 12, 2019
Decision date	Mar 13, 2020
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k191869/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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