

**K231902 GAMMEX PI Hybrid Micro (340002055)**Oct 20, 2023  
114 days to decisionK231902 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k231902/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Jun 28, 2023
Decision date	Oct 20, 2023
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	GAMMEX PI Hybrid Micro (340002060); GAMMEX PI Hybrid Micro (340002065); GAMMEX PI Hybrid Micro (340002070); GAMMEX PI Hybrid Micro (340002075); GAMMEX PI Hybrid Micro (340002080); GAMMEX PI Hybrid Micro (340002085); GAMMEX PI Hybrid Micro (340002090)

**APPLICANT**

---

Company	<b>Ansell Healthcare</b>
Location	Reno, NV, US
Contact	Carson Delaloye
510(k) history	1 submissions · 1 cleared · 2023-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231902/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 25, 2026