

K213289 Gammex® PI Plus Glove-in-Glove™ System Tested For Use with Chemotherapy DrugsMay 26, 2023
602 days to decisionK213289 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k213289/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Surgeon's Gloves (KGO) |
| Date received | Oct 1, 2021 |
| Decision date | May 26, 2023 |
| Days to decision | 602 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ansell Healthcare Products, LLC |
| Location | Dothan, AL, US |
| Contact | Tammy McGriff |
| 510(k) history | 26 submissions · 26 cleared · 2005-2023 |

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