

K910383 HPI SENSI-SHIELD GLOVE KITMar 20, 1991
49 days to decisionK910383 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k910383/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Surgeon's Gloves (KGO) |
| Date received | Jan 30, 1991 |
| Decision date | Mar 20, 1991 |
| Days to decision | 49 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Hpi, Inc. |
| Location | Newton Centre, MA, US |
| Contact | IMOGENE TIBBETS |
| 510(k) history | 6 submissions · 6 cleared · 1990-1993 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910383/>; Data sourced from FDA 510(k) public records (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. - Generated May 21, 2026