

**K011198 SENICARE ADVANTIX POWDER FREE
POLYURETHANE MEDICAL EXAMINATION GLOVE,
SENSICARE ADVANTIX POWDER FREE POLYURETHANE
DENTAL**May 17, 2001
28 days to decisionK011198 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k011198/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Apr 19, 2001 |
| Decision date | May 17, 2001 |
| Days to decision | 28 days |
| Third-party review | Yes |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Maxxim Medical, Inc. |
| Location | Hone Path, SC, US |
| Contact | JAMAL S ALNASER |
| 510(k) history | 2 submissions · 2 cleared · 2000-2001 |

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