

K911944 MEDI GUARD DENTAL BIBOct 4, 1991
156 days to decisionK911944 · Product code: **KKX** · General Hospital
Source: <https://www.510kdatabase.net/k911944/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Drape, Surgical (KKX) |
| Date received | May 1, 1991 |
| Decision date | Oct 4, 1991 |
| Days to decision | 156 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sancell, Inc. |
| Location | Canada, CA |
| Contact | DOREEN EDEY |
| 510(k) history | 5 submissions · 5 cleared · 1991-1991 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911944/> 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 July 7, 2026