

**K911953 MEDI GUARD SHEETS/UNDERLAYS**May 28, 1991  
27 days to decisionK911953 · Product code: **KME** · General Hospital  
Source: <https://www.510kdatabase.net/k911953/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bedding, Disposable, Medical (KME)
Date received	May 1, 1991
Decision date	May 28, 1991
Days to decision	27 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911953/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 7, 2026