

**K894599 SHIRT, OPERATING, SURGICAL**Aug 11, 1989  
22 days to decisionK894599 · Product code: **FYA** · General HospitalSource: <https://www.510kdatabase.net/k894599/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jul 20, 1989
Decision date	Aug 11, 1989
Days to decision	22 days
Third-party review	No

**APPLICANT**

---

Company	<b>Miroz Industries Co.</b>
Location	Staten Island, NY, US
Contact	ROSENTHAL
510(k) history	2 submissions · 2 cleared · 1989-1989

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894599/>; 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 8, 2026