

**K943809 MONOGARD FACE SHIELD**Nov 28, 1994  
116 days to decisionK943809 · Product code: **LYU** · General HospitalSource: <https://www.510kdatabase.net/k943809/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory, Surgical Apparel (LYU)
Date received	Aug 4, 1994
Decision date	Nov 28, 1994
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>White Knight Healthcare</b>
Location	Childersburg, AL, US
Contact	FRANK R DASTOLI
510(k) history	5 submissions · 5 cleared · 1994-1995

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943809/> 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 2, 2026