

K961454 AMMI MAGNI-GUARDJul 25, 1996
101 days to decisionK961454 · Product code: **LYU** · General Hospital
Source: <https://www.510kdatabase.net/k961454/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accessory, Surgical Apparel (LYU) |
| Date received | Apr 15, 1996 |
| Decision date | Jul 25, 1996 |
| Days to decision | 101 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | American Medical Mfg., Inc. |
| Location | Calabasas, CA, US |
| Contact | MIKE HOFTMAN |
| 510(k) history | 6 submissions · 6 cleared · 1992-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961454/> 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 4, 2026