

K953675 ALTADYNESep 28, 1995
52 days to decisionK953675 · Product code: **FNM** · General Hospital
Source: <https://www.510kdatabase.net/k953675/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mattress, Air Flotation, Alternating Pressure (FNM) |
| Date received | Aug 7, 1995 |
| Decision date | Sep 28, 1995 |
| Days to decision | 52 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Lumex, Inc. |
| Location | Bay Shore, NY, US |
| Contact | JAMES TERRACCIANO |
| 510(k) history | 8 submissions · 8 cleared · 1990-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953675/> 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 June 29, 2026