

K963906 PATIENT RESTRAINTSDec 2, 1996
63 days to decisionK963906 · Product code: **FMQ** · General Hospital
Source: <https://www.510kdatabase.net/k963906/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Restraint, Protective (FMQ) |
| Date received | Sep 30, 1996 |
| Decision date | Dec 2, 1996 |
| Days to decision | 63 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Safety Intl., Inc. |
| Location | Casselberry, FL, US |
| Contact | GEORGE BOLUKBAS |
| 510(k) history | 1 submissions · 1 cleared · 1996-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963906/> 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 6, 2026