

K882883 C-MASK(FLAT)Aug 10, 1988
30 days to decisionK882883 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k882883/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | Jul 11, 1988 |
| Decision date | Aug 10, 1988 |
| Days to decision | 30 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Promedica Products, Inc. |
| Location | Newport Beach, CA, US |
| Contact | LEE HAND |
| 510(k) history | 6 submissions · 6 cleared · 1988-1992 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k882883/>; 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 7, 2026