

K820237 COBE ACUFLEX FSN, #15-208Mar 10, 1982
41 days to decisionK820237 · Product code: **LFK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k820237/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Femoral (LFK) |
| Date received | Jan 28, 1982 |
| Decision date | Mar 10, 1982 |
| Days to decision | 41 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Cobe Laboratories, Inc. |
| Location | Mchenry, IL, US |
| Website | https://www.gambro.com |
| 510(k) history | 77 submissions · 77 cleared · 1976-1993 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k820237/>; 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 May 26, 2026