FDA 510(k) Premarket Notification

# K830677 BLOOD LINE SETS FOR HEMOFILTRATION

**CLEARED**

Apr 12, 1983
39 days to decision

K830677 · Product code: **FJK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k830677/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Tubing, Blood, With And Without Anti-regurgitation Valve (FJK) |
| Date received | Mar 4, 1983 |
| Decision date | Apr 12, 1983 |
| Days to decision | 39 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Gambro, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 86 submissions · 86 cleared · 1976-2009 |