

**K914271 GAMBRO ENGSTROM Y-FILTER WITH EDITH FLEX
(1500F)**Apr 13, 1992
202 days to decisionK914271 · Product code: **CAN** · Anesthesiology
Source: <https://www.510kdatabase.net/k914271/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Regulator, Pressure, Gas Cylinder (CAN) |
| Date received | Sep 24, 1991 |
| Decision date | Apr 13, 1992 |
| Days to decision | 202 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | C.G.H. Medical, Inc. |
| Location | Lakewood, CO, US |
| Contact | JEFFREY R SHIDEMAN |
| 510(k) history | 11 submissions · 11 cleared · 1991-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914271/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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