FDA 510(k) Premarket Notification

# K890489 EXTENSION SET W/FLOW REGULATOR

**CLEARED**

Jun 8, 1989
128 days to decision

K890489 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k890489/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Jan 31, 1989 |
| Decision date | Jun 8, 1989 |
| Days to decision | 128 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Baxter Healthcare Corp** |
| Location | Mchenry, IL, US |
| Contact | DENNIS OCWIEJA |
| 510(k) history | 505 submissions · 496 cleared · 1977-2019 |