

K890489 EXTENSION SET W/FLOW REGULATORJun 8, 1989
128 days to decisionK890489 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k890489/>**SUBMISSION DETAILS**

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|-----------------------|--|
| 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k890489/>; 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 17, 2026