

**K964850 SOLUTION ADMINISTRATION SET WITH 0.22 MICRON
HIGH PRESSURE EXTENDED LIFE FILTER**Feb 25, 1997
84 days to decisionK964850 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k964850/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Dec 3, 1996 |
| Decision date | Feb 25, 1997 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964850/> 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