

K063631 POLYPERF / POLYPERF SAFEOct 5, 2007
303 days to decisionK063631 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k063631/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Dec 6, 2006 |
| Decision date | Oct 5, 2007 |
| Days to decision | 303 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Laboratoires Perouse |
| Location | Ivry Le Temple, FR |
| Contact | MARIE NOELLE EROUT |
| 510(k) history | 1 submissions · 1 cleared · 2007-2007 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063631/> 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 June 26, 2026