

**K020424 V SET**Aug 29, 2003  
567 days to decisionK020424 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k020424/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received         | Feb 8, 2002                              |
| Decision date         | Aug 29, 2003                             |
| Days to decision      | 567 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Statement                                |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Hennig Enterprises Europe Srl</b>  |
| Location       | Perth, AU                             |
| Contact        | GEORGE O'NEIL                         |
| 510(k) history | 2 submissions · 2 cleared · 2003-2003 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k020424/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 2, 2026