

**K251500 MallyaG Injection Pen Adapter (MallyaG)**Jun 9, 2025  
25 days to decisionK251500 · Product code: **QOG** · General Hospital  
Source: <https://www.510kdatabase.net/k251500/>**SUBMISSION DETAILS**

---

|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Special                             |
| Device classification | Injection Data Capture Device (QOG) |
| Date received         | May 15, 2025                        |
| Decision date         | Jun 9, 2025                         |
| Days to decision      | 25 days                             |
| Third-party review    | No                                  |
| Combination product   | No                                  |
| PCCP authorized       | No                                  |
| Summary / Statement   | Summary                             |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Biocorp Production</b>             |
| Location       | Issoire, FR                           |
| Contact        | Alexia Garin                          |
| 510(k) history | 4 submissions · 4 cleared · 2022-2025 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251500/> 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 May 14, 2026