

**K910646 SUPERSERUM REAGENT (SSR)**May 10, 1991  
86 days to decisionK910646 · Product code: **JKA** · Chemistry  
Source: <https://www.510kdatabase.net/k910646/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                              |
| Submission type       | Traditional   |
| Device classification | Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA) |
| Date received         | Feb 13, 1991  |
| Decision date         | May 10, 1991  |
| Days to decision      | 86 days   |
| Third-party review    | No  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>International Technidyne Corp.</b>   |
| Location       | Walker, MI, US                          |
| Contact        | LES HEIMANN                             |
| 510(k) history | 47 submissions · 47 cleared · 1983-2013 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k910646/>; 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 June 8, 2026