

**K811150 URINE PREGNANCY TEST STANDARD/CONTR. PK**May 15, 1981  
18 days to decisionK811150 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k811150/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                |
| Submission type       | Traditional   |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received         | Apr 27, 1981  |
| Decision date         | May 15, 1981  |
| Days to decision      | 18 days   |
| Third-party review    | No  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Mallinckrodt Critical Care</b>                                       |
| Location       | Mchenry, IL, US   |
| Website        | <a href="https://www.mallinckrodt.com">https://www.mallinckrodt.com</a> |
| 510(k) history | 92 submissions · 92 cleared · 1976-1989                                 |

Mallinckrodt Critical Care is a medical device manufacturer based in McHenry, US. Now part of Mallinckrodt plc following a 2025 merger and subsequent restructuring, the company maintains a significant historical regulatory record in critical care and specialty medical devices. The company received FDA 510(k) clearances from total submissions between 1976 and 1989. Device clearances span anesthesiology, cardiovascular, gastroenterology, and general hospital categories. Notable cleared products include tracheal tubes, temperature monitoring systems, catheters, and related c...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k811150/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 21, 2026