

**K050983 IRMA TRUPOINT CREATININE CONTROL KIT**May 16, 2005  
27 days to decisionK050983 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k050983/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Apr 19, 2005
Decision date	May 16, 2005
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>International Technidyne Corporation</b>
Location	Roseville, MN, US
Contact	NANCY RING
510(k) history	1 submissions · 1 cleared · 2005-2005

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050983/> 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 29, 2026