

**K080436 RAPIDSENSE DRUGS OF ABUSE COCAINE (COC) 300  
DEVICE, MODEL 900-0052**Feb 11, 2009  
358 days to decisionK080436 · Product code: **DIO** · Toxicology  
Source: <https://www.510kdatabase.net/k080436/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Feb 19, 2008
Decision date	Feb 11, 2009
Days to decision	358 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Quantrx Biomedical Corporation</b>
Location	San Diego, CA, US
Contact	NATALIE J KENNEL
510(k) history	4 submissions · 4 cleared · 2007-2009

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080436/> Data sourced from FDA 510(k) public records (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. - Generated June 23, 2026