

**K101742 THERMO SCIENTIFIC CEDIA COCAINE OFT ASSAY**Apr 8, 2011  
290 days to decisionK101742 · Product code: **DIO** · Toxicology  
Source: <https://www.510kdatabase.net/k101742/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Jun 22, 2010
Decision date	Apr 8, 2011
Days to decision	290 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Microgenics Corp.</b>
Location	Concord, CA, US
Contact	LISA CHARTER
510(k) history	107 submissions · 106 cleared · 1985-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101742/> 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