

**K970510 INNOFLOUR TOPIRAMATE REAGENT SET**May 12, 1997  
90 days to decisionK970510 · Product code: **MSL** · Toxicology  
Source: <https://www.510kdatabase.net/k970510/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, Test, Topiramatee (MSL)    |
| Date received         | Feb 11, 1997                       |
| Decision date         | May 12, 1997                       |
| Days to decision      | 90 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Oxis Intl., Inc.</b>                 |
| Location       | Portland, OR, US                        |
| Contact        | LYNDA M TAYLOR                          |
| 510(k) history | 11 submissions · 11 cleared · 1995-1997 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970510/> 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 28, 2026