

**K982759 AUTO-LYTE COCAINE METABOLITE EIA, MODEL #  
1222U**Nov 20, 1998  
106 days to decisionK982759 · Product code: **DIO** · Toxicology  
Source: <https://www.510kdatabase.net/k982759/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                        |
| Submission type       | Traditional   |
| Device classification | Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO) |
| Date received         | Aug 6, 1998   |
| Decision date         | Nov 20, 1998  |
| Days to decision      | 106 days  |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>OraSure Technologies, Inc.</b>       |
| Location       | Bethlehem, PA, US                       |
| Contact        | R. SAM NIEDBALA                         |
| 510(k) history | 30 submissions · 29 cleared · 1996-2019 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982759/>; 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