

**K013882 OTI BENZODIAZEPINES INTERCEPT MICRO-PLATE
EIA MODEL #1110I**Apr 17, 2002
145 days to decisionK013882 · Product code: **JXM** · Toxicology
Source: <https://www.510kdatabase.net/k013882/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Benzodiazepine (JXM)
Date received	Nov 23, 2001
Decision date	Apr 17, 2002
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013882/> 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 May 14, 2026