

K895827 INNOFLUOR PHENYTOIN MANUAL FPIA REAGENT SETOct 31, 1989
29 days to decisionK895827 · Product code: **LGR** · Toxicology
Source: <https://www.510kdatabase.net/k895827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Diphenylhydantoin (total) (LGR)
Date received	Oct 2, 1989
Decision date	Oct 31, 1989
Days to decision	29 days
Third-party review	No

APPLICANT

Company	Innotron of Oregon, Inc.
Location	Mchenry, IL, US
Contact	CRAIG SMART
510(k) history	28 submissions · 28 cleared · 1980-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k895827/>. 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 29, 2026