FDA 510(k) Premarket Notification

K972331 INNOFLUOR GENTAMICIN ASSAY SYSTEM

CLEARED

Aug 1, 1997
39 days to decision

K972331 · Product code: **LGQ** · Toxicology
Source: https://www.510kdatabase.net/k972331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Phenobarbital (LGQ)
Date received	Jun 23, 1997
Decision date	Aug 1, 1997
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k972331/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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