

K843828 COBAS REAGENTS FOR TOBRAMYCIN & CALIBRAFeb 1, 1985
126 days to decisionK843828 · Product code: **LFW** · Toxicology
Source: <https://www.510kdatabase.net/k843828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Tobramycin (LFW)
Date received	Sep 28, 1984
Decision date	Feb 1, 1985
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
510(k) history	296 submissions · 296 cleared · 1983-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k843828/> 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 23, 2026