

K850808 COBAS FP REAGENTS FOR QUINIDINEMar 25, 1985
26 days to decisionK850808 · Product code: **LBZ** · Toxicology
Source: <https://www.510kdatabase.net/k850808/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Quinidine (LBZ)
Date received	Feb 27, 1985
Decision date	Mar 25, 1985
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k850808/> 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