

K830480 ABUSCREEN RADIOIMMUNOASSAY-COCAINE METAMar 24, 1983
37 days to decisionK830480 · Product code: **KLN** · Toxicology
Source: <https://www.510kdatabase.net/k830480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Cocaine Metabolite (KLN)
Date received	Feb 15, 1983
Decision date	Mar 24, 1983
Days to decision	37 days
Third-party review	No

APPLICANT

Company	Hoffmann-La Roche, Inc.
Location	Mchenry, IL, US
Website	https://www.roche.com
510(k) history	49 submissions · 49 cleared · 1976-1985

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k830480/>, 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