

**K032936 DIRECT LDL CHOLESTEROL LIQUID COLOR AND
STANBIO DIRECT HDL/LDL CHOLESTEROL CALIBRATOR**Mar 12, 2004
172 days to decisionK032936 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k032936/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Sep 22, 2003
Decision date	Mar 12, 2004
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stanbio Laboratory
Location	Mchenry, IL, US
Contact	ADAObI OGUCHI
510(k) history	47 submissions · 47 cleared · 1977-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032936/> 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