

**K050823 DIRECT HDL CHOLESTEROL AND DIRECT HDL/LDL
CALIBRATOR**Jul 26, 2005
117 days to decisionK050823 · Product code: **LBR** · Chemistry
Source: <https://www.510kdatabase.net/k050823/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Hdl (LBR)
Date received	Mar 31, 2005
Decision date	Jul 26, 2005
Days to decision	117 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Teco Diagnostics
Location	Placentia, CA, US
Contact	JIAN VAECHES
510(k) history	51 submissions · 51 cleared · 1993-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050823/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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