

K110394 ATAC SERUM CALIBRATOR (DIRECT BILIRUBIN AND IRON)Jun 9, 2011
118 days to decisionK110394 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k110394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Feb 11, 2011
Decision date	Jun 9, 2011
Days to decision	118 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Vital Diagnostics (Manufacturing) PtyLtd
Location	Noble Park, AU
Contact	MELITA LAMBIRIS
510(k) history	5 submissions · 5 cleared · 2010-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110394/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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