

K100060 EON 100 CHEMISTRY ANALYZER WITH ISE , MODEL 77105, BICARBONATE REAGENT, MODEL 77475Dec 15, 2010
338 days to decisionK100060 · Product code: **KHS** · Chemistry
Source: <https://www.510kdatabase.net/k100060/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic, Carbon-dioxide (KHS)
Date received	Jan 11, 2010
Decision date	Dec 15, 2010
Days to decision	338 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/k100060/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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