

K120626 EON CALCIUM REGENTAug 22, 2012
174 days to decisionK120626 · Product code: **CJY** · Chemistry
Source: <https://www.510kdatabase.net/k120626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Azo Dye, Calcium (CJY)
Date received	Mar 1, 2012
Decision date	Aug 22, 2012
Days to decision	174 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

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