

K071648 EXTENDSURE LYOPHILIZED HBA1C LINEARITY CONTROLSAug 22, 2007
65 days to decisionK071648 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k071648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jun 18, 2007
Decision date	Aug 22, 2007
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Canterbury Scientific , Ltd.
Location	Christchurch, NZ
Contact	MAURICE OWEN
510(k) history	3 submissions · 3 cleared · 2002-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071648/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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