

K011389 HEMOGLOBIN F & A2 CONTROL (BETA-THALASSAEMIA CONTROL)

Jun 21, 2001
45 days to decision

K011389 · Product code: **JCM** · Hematology
Source: <https://www.510kdatabase.net/k011389/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Hemoglobin, Abnormal (JCM)
Date received	May 7, 2001
Decision date	Jun 21, 2001
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Canterbury Health Laboratories
Location	Christchurch, Canterbury, NZ
Contact	MAURICE OWEN
510(k) history	1 submissions · 1 cleared · 2001-2001

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k011389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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