

K050576 MICROALBUMIN TIA REAGENTApr 21, 2005
45 days to decisionK050576 · Product code: **DDZ** · Chemistry
Source: <https://www.510kdatabase.net/k050576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Albumin, Fitc, Antigen, Antiserum, Control (DDZ)
Date received	Mar 7, 2005
Decision date	Apr 21, 2005
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary
Other names	MALB CALIBRATOR SET 200; MALB CONTROL-L, CONTROL-H

APPLICANT

Company	Good Biotech Corp.
Location	Taichung, TW
Contact	VICTOR CHIOU
510(k) history	8 submissions · 8 cleared · 2002-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050576/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026