

K013643 AUSAM TOTAL ALBUMIN ASSAYAug 14, 2003
647 days to decisionK013643 · Product code: **JIQ** · Chemistry
Source: <https://www.510kdatabase.net/k013643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Turbidimetric Method, Protein Or Albumin (urinary, Non-quant.) (JIQ)
Date received	Nov 5, 2001
Decision date	Aug 14, 2003
Days to decision	647 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ausam Biotechnologies, Inc.
Location	New York, NY, US
Contact	LYNN ROLAND
510(k) history	1 submissions · 1 cleared · 2003-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013643/> 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 29, 2026