

K140436 ARCHITECT GALECTIN-3 Reagent Kit, ARCHITECT GALECTIN-3 CALIBRATORS, ARCHITECT GALECTIN-3 CONTROLS

Dec 23, 2014
305 days to decision

K140436 · Product code: **OSX** · Chemistry
Source: <https://www.510kdatabase.net/k140436/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Galectin-3 In Vitro Diagnostic Assay (OSX)
Date received	Feb 21, 2014
Decision date	Dec 23, 2014
Days to decision	305 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujirebio Diagnostics, Inc.
Location	North Caldwell, NJ, US
Contact	STACEY DOLAN
510(k) history	45 submissions · 43 cleared · 1989-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k140436/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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