

**K013147 GLUCOSE CONTROL SOLUTION FOR THERASENSE
FREESTYLE**

Oct 24, 2001
34 days to decision

K013147 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k013147/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 20, 2001
Decision date	Oct 24, 2001
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionostics, Inc.
Location	Mchenry, IL, US
Contact	KATHY STORRO
510(k) history	49 submissions · 49 cleared · 1983-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k013147/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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