

**K151487 Diatron Pictus 700 Clinical Chemistry Analyzer,
Diatron ISE, Diatron Glucose Hexokinase Method**

Jan 14, 2016
226 days to decision

K151487 · Product code: CFR · Chemistry
Source: <https://www.510kdatabase.net/k151487/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Jun 2, 2015
Decision date	Jan 14, 2016
Days to decision	226 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diatron U.S., Inc.
Location	Lenexa, KS, US
Contact	Frank Matusazak
510(k) history	3 submissions · 3 cleared · 2012-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k151487/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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