

**K103531 PRESTIGE 24I**Dec 1, 2011  
365 days to decisionK103531 · Product code: **CFR** · Chemistry  
Source: <https://www.510kdatabase.net/k103531/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Dec 1, 2010
Decision date	Dec 1, 2011
Days to decision	365 days
Third-party review	No
Summary / Statement	Summary
Other names	BIOLIS 24I; MGC 240

**APPLICANT**

---

Company	<b>Tokyo Boeki Medisys, Inc.</b>
Location	Durham, NC, US
Contact	James M Clinton
510(k) history	2 submissions · 2 cleared · 2011-2012

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k103531/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 15, 2026