

**K040958 PRESTIGE MODELS 24I AND 400 AND MGC MODEL  
240**Feb 15, 2005  
308 days to decisionK040958 · Product code: **JJE** · Chemistry  
Source: <https://www.510kdatabase.net/k040958/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE)
Date received	Apr 13, 2004
Decision date	Feb 15, 2005
Days to decision	308 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tokyo Boeki Medical System , Ltd.</b>
Location	Raleigh, NC, US
Contact	James M Clinton
510(k) history	1 submissions · 1 cleared · 2005-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040958/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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