

K110520 BIOLIS 12IMar 23, 2012
394 days to decisionK110520 · Product code: **CEM** · Chemistry
Source: <https://www.510kdatabase.net/k110520/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Potassium (CEM)
Date received	Feb 23, 2011
Decision date	Mar 23, 2012
Days to decision	394 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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