

**K183375 Yumizen C1200, Yumizen C1200 Glucose HK, Sodium Electrode, Potassium Electrode, Chloride Electrode**Feb 12, 2019  
68 days to decisionK183375 · Product code: **JJE** · Chemistry  
Source: <https://www.510kdatabase.net/k183375/>**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	Dec 6, 2018
Decision date	Feb 12, 2019
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Horiba, Ltd.</b>
Location	Irvine, CA, US
Contact	Naoyuki Nomura
Website	<a href="http://www.horiba.com">http://www.horiba.com</a>
510(k) history	2 submissions · 2 cleared · 2002-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183375/> 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 19, 2026