

**K192920 Oragene®•Dx**Jan 14, 2020  
90 days to decisionK192920 · Product code: **OYJ** · Chemistry  
Source: <https://www.510kdatabase.net/k192920/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna Specimen Collection, Saliva (OYJ)
Date received	Oct 16, 2019
Decision date	Jan 14, 2020
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DNA Genotek, Inc.</b>
Location	Ottawa Ontario, CA
Contact	Austin Udacor
510(k) history	7 submissions · 6 cleared · 2011-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192920/> 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 May 26, 2026