

K212745 ORAcollect®DxOct 27, 2022
423 days to decisionK212745 · Product code: **OYJ** · Chemistry
Source: <https://www.510kdatabase.net/k212745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna Specimen Collection, Saliva (OYJ)
Date received	Aug 30, 2021
Decision date	Oct 27, 2022
Days to decision	423 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212745/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026