

K152464 ORAcollect.DxMay 26, 2016
269 days to decisionK152464 · Product code: **OYJ** · Chemistry
Source: <https://www.510kdatabase.net/k152464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna Specimen Collection, Saliva (OYJ)
Date received	Aug 31, 2015
Decision date	May 26, 2016
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152464/> 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