

K141410 ORAGENE DX OGD-500.001Feb 19, 2015
266 days to decisionK141410 · Product code: **OYJ** · Chemistry
Source: <https://www.510kdatabase.net/k141410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna Specimen Collection, Saliva (OYJ)
Date received	May 29, 2014
Decision date	Feb 19, 2015
Days to decision	266 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

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