DNAgenotek™

Product change notification

Products affected: ORAgene®•Dx

Catalog number: OGD-500, OGD-510, OGD-575
OGD-600, OGD-610 and OGD-675

Description: Oragene®•Dx product family

Effective date of change: January 14, 2020

Customer action: None.

Change description:

DNA Genotek has obtained general clearance for our Oragene•Dx product family, making this the first and only saliva collection device that can be used for prescription or over-the-counter use by healthcare or non-healthcare professionals.

Reason for change:

1. Extending utility of the Oragene•Dx product family to allow customers to use devices within their test protocol without needing to provide information on Oragene•Dx devices in FDA submissions.
2. Enable use of devices by users of all ages including paediatrics.
3. Ability to offer additional customization options including branding of labeling and marketing materials.

Please contact **info@dnagenotek.com** if you have any issues or concerns pertaining to this product change notification.