DNA Genotek Inc.
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November 3, 2021

Re: DEN200040
Trade/Device Name: OMNIgene•GUT Dx
Regulation Number: 21 CFR 866.2952
Regulation Name: Device to preserve and stabilize relative abundances of microbial nucleic acids in clinical samples.
Regulatory Class: Class II
Product Code: QPO
Dated: June 12, 2020
Received: June 15, 2020

Dear Austin Udocor:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the OMNIgene•GUT Dx, a prescription device with the following indications for use:

> OMNIgene•GUT Dx is intended for the non-invasive collection of human fecal samples and the stabilization of DNA from the bacterial community for subsequent assessment of the microbiome profile by an assay validated for use with OMNIgene•GUT Dx.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the OMNIgene•GUT Dx, and substantially equivalent devices of this generic type, into Class II under the generic name device to preserve and stabilize relative abundances of microbial nucleic acids in clinical samples.

FDA identifies this generic type of device as:

> **Device to preserve and stabilize relative abundances of microbial nucleic acids in clinical samples.** A device to preserve and stabilize relative abundances of microbial nucleic acids in clinical samples is a device that consists of a container and reagents intended to stabilize microbial nucleic acids for the subsequent assessment of the relative abundance of microbial nucleic acids (i.e., microbiome) in human specimens by an assay validated for use with the device. The device may also be indicated for sample collection. The device is not intended for preserving morphology or viability of microorganisms.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On June 15, 2020, FDA received your De Novo requesting classification of the OMNIgene•GUT Dx. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the OMNIgene•GUT Dx into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the OMNIgene•GUT Dx can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Identified Mitigations

Identified Risks to Health	Mitigation Measures
Failure to correctly operate the device leading to inadequate sample collection.	Certain labeling information, including warnings and device descriptions. Certain design verification and validation studies.
Failure to stabilize microbial nucleic acid resulting in an inaccurate assay result.	Certain design verification and validation studies.
Device use with unvalidated or incompatible assays leading to inaccurate assay results and improper patient management.	Certain labeling information, including warnings, device descriptions, and study information.
Malfunction of the collection device may lead to possible exposure to infectious pathogens by laboratorians or individuals collecting fecal samples.	Certain labeling information, including warnings and device descriptions.

In combination with the general controls of the FD&C Act, the device to preserve and stabilize relative abundances of microbial nucleic acids in clinical samples is subject to the following special controls:

(1) The intended use on the device's label and labeling required under 21 CFR 809.10 must include a detailed description of the type(s) of human specimens intended for collection and preservation, and the characteristics of the microbial population intended for subsequent analysis.

(2) The labeling required under 21 CFR 809.10(b) must include:
- (i) A detailed device description, including reagents, ancillary reagents required but not provided, and all other parts that make up the device.
- (ii) A warning statement that the device is not for the detection of specific microbial pathogens.
- (iii) A warning statement that the device should only be used with legally marketed assays that are indicated for use with the device, including, as appropriate, indicated for the relevant storage and transport conditions.
- (iv) Description of the microorganisms used for studies, including the results and performance summaries, required under paragraph (3)(i).

(3) Design verification and validation must include:
- (i) Detailed documentation and results from studies used for device validation. This detailed documentation must include a detailed identification of each of the following (which must be representative of the spectrum of situations in which the device might be used that are within the scope of the device's intended use): the panel of microorganisms, the extraction platforms, the assay protocols used to measure the stabilization of relative ratios (relative abundance) of the microorganisms in the sample, and the bioinformatic pipelines used in the validation studies for the determination of relative abundances of preserved nucleic acids.
- (ii) For devices intended for the collection of samples, detailed documentation and results from studies that demonstrate the device's usability, including user collection studies that demonstrate that the user instructions are appropriate for the intended collection methods (e.g., self-collection or clinician/laboratory collection) and users.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the device to preserve and stabilize relative abundances of microbial nucleic acids in clinical samples they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Alyxandria Schubert at 240-402-2853.

Sincerely,

Uwe Scherf -S

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