DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 14, 2017

ILLUMINA, INC.
C/O DAVE KERN, SENIOR DIRECTOR, REGULATORY AFFAIRS
5200 ILLUMINA WAY
SAN DIEGO, CA 92122

Re: k133136
MiSeqDx Universal Kit 1.0
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 862.3800
Regulation Name: Reagents for molecular diagnostic instrument test systems
Regulatory Classification: Class I
Product Code: PFT
Dated: October 3, 2013
Received: October 4, 2013

Dear Ms. Kiviharju:

This letter corrects our letter dated November 19, 2013.

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 MiSeqDx Universal Kit 1.0, a prescription device. The intended use of the MiSeqDx Universal Kit 1.0 is

> The MiSeqDx Universal Kit 1.0 is a set of reagents and consumables used in the processing of human genomic DNA samples derived from peripheral whole blood, and in the subsequent targeted re-sequencing of the resulting sample libraries. User-supplied analyte specific reagents are required for the preparation of libraries targeting specific genomic regions of interest. The MiSeqDx Universal Kit 1.0 is intended for use with the MiSeqDx instrument.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class I. This order, therefore, classifies the MiSeqDx Universal Kit 1.0, and substantially equivalent devices of this generic type, into class I under the generic name, "Reagents for molecular diagnostic instrument test systems."

FDA identifies this generic type of device as: Reagents for Molecular Diagnostic Test Systems

> Reagents for Molecular Diagnostic Test Systems are identified as reagents other than analyte specific reagents used as part of molecular diagnostic test systems, such as polymerases,

> nucleotides and nucleotide mixes, master mixes in which individual reagents are optimized to be used together, and labeled nucleic acid molecules.

Section 513(f)(2) of 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 new 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, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. 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** classifying the device type.

On October 4, 2013, FDA received your *de novo* request for classification of the MiSeqDx Universal Kit 1.0 into class I. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the MiSeqDx Universal Kit 1.0 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 the MiSeqDx Universal Kit 1.0 intended for use as follows

> The MiSeqDx Universal Kit 1.0 is a set of reagents and consumables used in the processing of human genomic DNA samples derived from peripheral whole blood, and in the subsequent targeted re-sequencing of the resulting sample libraries. User-supplied analyte specific reagents are required for the preparation of libraries targeting specific genomic regions of interest. The MiSeqDx Universal Kit 1.0 is intended for use with the MiSeqDx instrument.

can be classified in class I. FDA believes that class I (general) controls provide reasonable assurance of the safety and effectiveness of the device type.

Table – Identified Potential Risk and Required Mitigation

Identified Potential Risk	**Required Mitigation**
Inaccurate test results due to inconsistently manufactured test system reagents	General controls, including current good manufacturing practices

The Reagents for Molecular Diagnostic Instrument Test Systems are subject to the general controls of the FD&C Act. Section 510(l) of the FD&C Act (21 U.S.C. 360(l)) provides that a class I device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does not meet these criteria and, therefore, premarket notification is not required for the device. Thus, persons who intend to market this device need not submit a premarket notification containing information on the Reagents for Molecular Diagnostic Instrument Test Systems they intend to market prior to marketing the device subject to the limitations on exemptions in 21 CFR 862.9.

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.

If you have any questions concerning this classification order, please contact Kellie Kelm at 301-796-6145.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health