DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Illumina, Inc.
c/o Mr. Jay T. Flatley
President & CEO
9885 Towne Centre Drive
San Diego, CA 92121-1975

JUN 10 2010

RE: Illumina® Infinium HumanHap550 array

Dear Mr. Flatley:

The United States Food and Drug Administration (FDA) has determined that your firm manufactures the Illumina® Infinium HumanHap550 array used by deCODE Genetics and 23andMe to provide genetic information to their customers. The Illumina® Infinium HumanHap550 array is a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h) because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body.

In 1976, Congress enacted the Medical Device Amendments (MDA), which amended the Act to provide for premarket regulation of medical devices intended for use in humans. This premarket review of medical devices enables FDA to protect the public from medical products that may pose an unreasonable risk of harm. It is important that they be analytically and clinically accurate so that individuals are not misled by incorrect test results or unsupported clinical interpretations. Premarket review allows for an independent and unbiased assessment of a diagnostic test's ability to generate test results that can reliably be used to support good healthcare decisions.

Although Illumina, Inc. has received FDA clearance or approval for several of its devices, we note that the Illumina® Infinium HumanHap550 array is not one of them and is labeled "For Research Use Only". Yet Illumina is knowingly providing the HumanHap550 array to 23andMe and deCODE Genetics for clinical diagnostic use without FDA clearance or approval.

During a meeting between Illumina and FDA on July 31, 2009, you stated that 23andMe and deCODE genetics both order Illumina arrays for use in their personal genome diagnostic tests. For example, the 23andMe Personal Genome Service™ uses both the Illumina® Infinium HumanHap550 array and a custom array for its Personal Genome Service™. The 23andMe Personal Genome Service™ and the deCODEme Genome Scan both provide an estimate of an individual's risk for various diseases or conditions based on genotypic data.

Mr. Jay Flatley
Illumina, Inc

We are not aware that you have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). In addition, we are not aware that you have notified the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency. 21 C.F.R. 807.81(b).

You should take prompt action to respond to this letter. If you would like to meet with us to discuss whether there are tests you are promoting that do not require review by FDA and what information you would need to submit in order for your product to be legally marketed for the other uses, let us know and we will schedule a meeting with you. Please direct your questions and response to: **James L. Woods, Food and Drug Administration, 10903 New Hampshire Avenue, WO66-5688, Silver Spring, MD 20993 or** facsimile at **(301) 847-8514.**

General information on obtaining approval or clearance for devices is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html.

This letter pertains only to the issue of premarket review for your device and does not necessarily address other obligations you have under the law. FDA is available to discuss other obligations for medical device manufacturers with you.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Device and Radiological Health