DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mark B. Carbeau
Chief Executive Officer
Interleukin Genetics, Inc.
135 Beaver Street
Waltham, MA 02452

NOV 04 2015

Document Number: GEN1500806

Dear Mr. Carbeau;

It has come to our attention that you are currently marketing the *PerioPredict® Genetic Test, Osteoarthritis Genetic Test, and Weight Management Genetic Test,* which are intended to *identify individuals with genetic predisposition for increased risk to diabetes and heart attack, Osteoarthritis Associated Conditions, and obesity-related genotype for weight loss, respectively.* The *PerioPredict® Genetic Test, Osteoarthritis Genetic Test, and Weight Management Genetic Test,* appear to meet the definition of devices as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act.

We have conducted a review of our files, and have been unable to identify any Food and Drug Administration (FDA) clearance number for the *PerioPredict® Genetic Test, Osteoarthritis Genetic Test, and Weight Management Genetic Test.* We request that you provide us with the FDA clearance number for the *PerioPredict® Genetic Test, Osteoarthritis Genetic Test, and Weight Management Genetic Test.* If you do not believe that you are required to obtain FDA clearance for the *PerioPredict® Genetic Test, Osteoarthritis Genetic Test, and Weight Management Genetic Test,* please provide us with the basis for that determination.

This is also to acknowledge your response letter dated August 2, 2010 to our inquiry letter regarding "the Inherent Health testing service (the "Tests"), that you have claimed as "Laboratory Developed Tests." However, it appears that at the present time, your firm is offering these tests under a Direct-to-Consumer model.

We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

Mr. Carbeau
Interleukin Genetics, Inc.

James L. Woods, WO66-5688
Deputy Director
Patient Safety and Product Quality
Office of *In Vitro* Diagnostics and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

If you have questions relating to this matter, please feel free to call E. Caroline Satyadi at 240-402-6582, or log onto our web site at www.fda.gov for general information relating to FDA device requirements.

Sincerely yours,

James L. Woods
Deputy Director Patient Safety
And Product Quality
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and
Radiological Health