DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Brian Pollock
President and Chief Executive Officer
Kailos Genetics, Inc.
601 Genome Way
Huntsville, AL 35806
Document Number: GEN1500781

NOV 16 2015

Dear Mr. Pollock,

It has come to our attention that you are currently marketing the Kailos Test, which is intended to analyze multiple genes for indications of disease risk as well as the response to over 50 types of medicine. The Kailos Test appears to meet the definition of a device 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 Kailos Test. We request that you provide us with the FDA clearance number for the Kailos Test. If you do not believe that you are required to obtain FDA clearance for the Kailos Test, please provide us with the basis for that determination.

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

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

Mr. Brian Pollock
Kailos Genetics, Inc.

If you have questions relating to this matter, please feel free to call Mary Galloway at 301-796-5115, 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