



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.

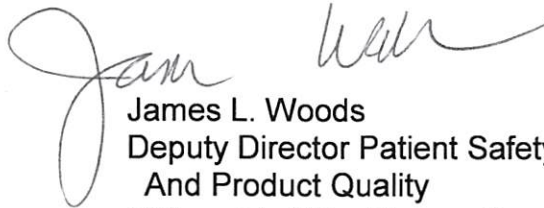
We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

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](http://www.fda.gov) for general information relating to FDA device requirements.

Sincerely yours,

A handwritten signature in black ink, appearing to read "James L. Woods". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

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