DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 16 2016

Mr. Warren Little, CEO
Mr. Rick White, Founder
Sure Genomics, Inc.
9533 South 700 East, Suite 204
Sandy, UT 84070
Document Number: GEN1600055

Dear Mr. Little and Mr. White,

It has come to our attention that you have begun preordering for the SureDNA™ test, which is intended to collect saliva samples for DNA sequencing and reporting of patient information such as disease risks and likelihood of drug reactions. The SureDNA™ 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 SureDNA™ test. We request that you provide us with the FDA clearance number for the SureDNA™ test. If you do not believe that you are required to obtain FDA clearance for the SureDNA™ 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

If you have questions relating to this matter, please feel free to call Joshua Levin at 301-796-6695, 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