



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

Dr. Grant A. Bitter
Chief Executive Officer
Genomic Express, Inc.
725-H Lakefield Rd.
Westlake Village, CA 91361

DEC 07 2015

Document Number: GEN1500805

Dear Dr. Bitter:

It has come to our attention that you are currently marketing direct-to-consumer tests for Clopidogrel (Plavix®) response, Warfarin (Coumadin®) sensitivity, and Tamoxifen (Nolvadex®) response, which are intended to determine whether a patient has genetic variants indicative of the ability to metabolize and/or respond effectively to these medications.

These tests for Clopidogrel (Plavix®) response, Warfarin (Coumadin®) sensitivity, and Tamoxifen (Nolvadex®) response appear 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(s) for the Clopidogrel (Plavix®) response, Warfarin (Coumadin®) sensitivity, and Tamoxifen (Nolvadex®) response tests. We request that you provide us with the FDA clearance number for these devices. If you do not believe that you are required to obtain FDA clearance for the devices, please provide us with the basis for that determination.

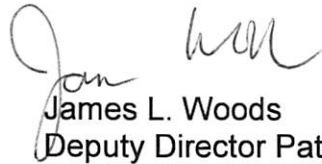
We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

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

Dr. Grant Bitter
Genome Express, Inc.

If you have questions relating to this matter, please feel free to call James Nadeau, Ph.D., at 240-402-6638 or log onto our web site at 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 written in a cursive style with a large initial "J" and "W".

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