DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Bob Bean
President and CEO
Harmonyx
8110 Cordova Rd., Suite 119
Cordova, TN 38016

NOV 16 2015

Document Number: GEN1500832

Dear Mr. Bean:

It has come to our attention that you are currently marketing the HarmonyX tests for antiplatelets, statins, ADHD, and pain, which appear to be are marketed under a direct-to-consumer model and are intended to allow the patient's pharmacist and physician to quickly and easily identify whether the patient can safely continue taking their medicine, or whether they need to find a new course of treatment. The HarmonyX tests 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 for the HarmonyX tests. We request that you provide us with the FDA clearance number for the HarmonyX tests. If you do not believe that you are required to obtain FDA clearance for the HarmonyX tests, 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. Bob Bean
Harmonyx

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