



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

Mr. Randy Farr  
Chief Executive Officer  
Healthspek LLC  
6431 Annandale Cove  
Brentwood, TN 37027

**DEC 07 2015**

Document Number: GEN1500807

Dear Mr. Farr:

It has come to our attention that you are currently marketing a direct-to-consumer test the Healthspek PGT, which is intended to test genes that affect drug metabolism. The Healthspek PGT 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 Healthspek PGT. We request that you provide us with the FDA clearance number for the Healthspek PGT. If you do not believe that you are required to obtain FDA clearance for the Healthspek PGT, please provide us with the basis for that determination.

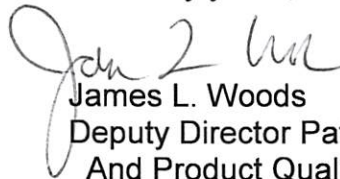
We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

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. Randy Farr,  
Healthspek LLC

If you have questions relating to this matter, please feel free to call Freddy Tita-Nwa at 301-796-6213, 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 "John L. Woods", written over the printed name.

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