



Wayne Lindsay  
Founder and CEO  
Solopap International Limited  
1000 North Green Valley Pkwy  
Suite 440-256  
Henderson, NV 89704

FEB 17 2016

Document Number: GEN1600021

Dear Mr. Lindsay:

It has come to our attention that you are currently marketing the SoloPap™ Home HPV&PAP Test, which is available for purchase via PayPal and intended to be used for the self collection of a cervical sample as well as to perform a self-administered HPV and PAP test. The SoloPap™ Home HPV&PAP 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) approval number for the SoloPap™ Home HPV&PAP Test. We request that you provide us with the FDA approval number for the SoloPap™ Home HPV&PAP Test. If you do not believe that you are required to obtain FDA approval for the SoloPap™ Home HPV&PAP Test, please provide us with the basis for that determination. Also, please provide a sample laboratory report which provides the test results to the medical practitioners.

Please notify the FDA in writing within 15 business days from the date you received this letter of the specific steps your firm has taken to address the issue identified above. Your firm's response should refer to GEN1600021 and be sent to:

James L. Woods, WO66-4684  
Deputy Director  
Patient Safety and Product Quality  
Office of *In Vitro* Diagnostics and Radiological Health  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Wayne Lindsay  
Solopap International Limited

If you have questions relating to this matter, please feel free to call John Xu, Ph.D., at 301-796-5918, or log onto our web site at [www.fda.gov](http://www.fda.gov) for general information relating to FDA device requirements.

Sincerely yours,

James L. Woods -A  
2016.02.16 15:54:51 -05'00'

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