



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

Mr. Rajasingam S Jeyendran  
DNA-Cardiocheck, Inc.  
2292 Regency Woods Drive  
Lisle, IL 60523

NOV 02 2015

Document Number: GEN1500296

Dear Mr. Rajasingam Jeyendran:

It has come to our attention that you are currently marketing a direct-to-consumer test, the DNA-CardioCheck, which is intended to test for DNA genetic markers linked to thrombophilia, deep-vein thrombosis, cardiovascular disease and stroke. The DNA-CardioCheck 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 FDA clearance number for the DNA-CardioCheck. We request that you provide us with the FDA clearance number for this device. If you do not believe that you are required to obtain FDA clearance for the device, please provide us with the basis for that determination.

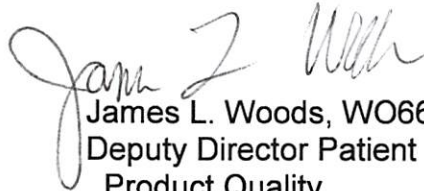
We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

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. Rajasingam Jeyendran  
DNA-CardioCheck

If you have questions relating to this matter, please feel free to call James Nadeau at 240-402-6638, 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 that reads "James L. Woods". The signature is written in a cursive style with a large initial "J" and "W".

James L. Woods, WO66-5688  
Deputy Director Patient Safety and  
Product Quality  
Office of *In Vitro* Diagnostics and  
Radiological Health  
Center for Devices and  
Radiological Health